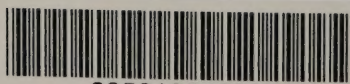




Human Fertilisation and Embryology Authority

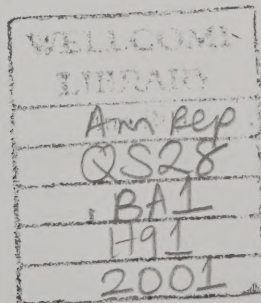
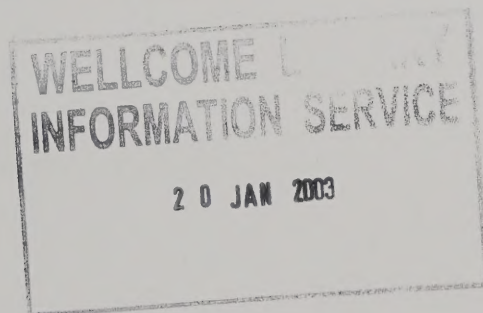
Tenth Annual Report and
Accounts 2001



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Human Fertilisation and Embryology Authority

Tenth Annual Report and Accounts 2001



Human Fertilisation and Embryology Authority
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This report covers the year beginning November 1999 with a forward look for the year beginning November 2000.

All information contained was correct as of 31 August 2001.

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Chairman's Letter

The Human Fertilisation and Embryology Authority has now reached its tenth year of existence. It has achieved much in the past decade to assure patients that the treatment received at licensed centres is of a high standard and that the advances in reproductive technology move in step with public opinion. The HFEA has been able to do this as a consequence of the mutually supportive relationships that it has built in an Assisted Reproductive Technology community which includes clinicians, patients, scientists, nurses, counsellors as well as professional and patient groups. The Code of Practice, now in its fifth edition, is well understood in the profession. However, the role of the regulator is evolving and nowhere more so than in this fast-moving area of medical science. As we move into the future there will be little time for congratulating ourselves on what has been achieved; indeed the HFEA has already entered a new phase, developing and improving its regulatory mechanisms.

We have been giving these improvements much consideration. Amongst other things, we have been looking at ways in which we can work with centres to build on existing quality systems in clinical and laboratory procedures, as well as developing more formal quality assurance systems for our inspections which will involve additional training for inspector co-ordinators and external inspectors. This is not about making major changes to an existing system that we know works well, but rather about changes that will, with the help of licensed centres, ensure that high standards are universally and consistently applied.

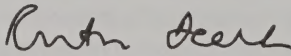
Further challenges are expected during the coming year. For some time we have been working on regulation for the present and future development of pre implantation genetic diagnosis. We have been working with the Human Genetics Commission on this issue and have given careful consideration to the responses we received to the public consultation held more than a year ago. This is a significant issue as it represents an increasing focus on genetic disease, rather than fertility, as a reason for treatment.

In January 2001 we were pleased that Parliament chose to approve new regulations allowing the purposes for which human embryo research may be permitted to be extended to include increasing knowledge about serious disease and the developing treatments for such diseases. This has demonstrated the confidence Parliament has in our ability to regulate this highly sensitive area of research. We have made changes to our existing systems in readiness for new applications, and our experience over the past ten years, and the systems that we have developed during this period, will stand us in good stead.

It is essential that in all the areas in which we act we have a full understanding of the medical, scientific, ethical and social implications of new developments. We greatly value the input of professional and patient organisations, either through consultation or through the development of their own professional standards and guidelines. Our relationship with such organisations is an essential one, and our links between them are now well established.

As Chairman of the Authority I am very proud of what has been accomplished over the past ten years. I am pleased that the second Quinquennial Review of the Authority's work, approved by the Minister this year, recognised the value of the work we do and the need for continuing independent regulation of this field of medicine.

Finally, it is with great sadness that I will be retiring in March as the HFEA's Chairman. I have greatly enjoyed this tremendously challenging and rewarding role. This has largely been thanks to the hard work and dedication of past and present Members and Executive Staff who have all helped to make the HFEA the respected regulatory body it is today. I would particularly like to thank Allan Templeton and Moira Coath who have left the Authority since the last Annual Report. I would also like to welcome our new Chief Executive, Maureen Dalziel, as well as new Members Tom Baldwin, Ivor Brecker, Iain Cameron and Simon Jenkins who I am sure will continue the excellent work of their predecessors.

A handwritten signature in black ink, appearing to read 'Ruth Deech'.

Ruth Deech
Chairman

1. The Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority (HFEA) was set up in August 1991 by the Human Fertilisation and Embryology Act 1990 (HFE Act). The first statutory body of its kind in the world, the HFEA's creation reflected public and professional unease about the potential future of human embryo research and infertility treatments, and a widespread desire for statutory regulation of this highly sensitive area. The recommendation for such a body had come from the 1984 report of the Committee of Inquiry into Human Fertilisation and Embryology (the 'Warnock' report).

The HFEA's principal tasks are to license and monitor those clinics that carry out *in vitro* fertilisation (IVF), donor insemination (DI) and human embryo research. The HFEA also regulates the storage of gametes (sperm and eggs) and embryos.

The HFEA's other statutory functions are:

- to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;
- to keep a formal register of information about donors, treatments and children born from those treatments;
- to publicise its role and provide relevant advice and information to patients, donors and clinics; and
- to keep under review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act and advise the Secretary of State, if asked, about those matters.

Underlying all its activities is the HFEA's determination to safeguard all relevant interests – patients, children, doctors and scientists, the wider public – and future generations.

THE HFEA'S MEMBERSHIP AND ITS EXECUTIVE

HFEA Members are appointed by UK Health Ministers in accordance with the guidance from the Commissioner for Public Appointments (Nolan guidelines). The Members determine the HFEA's policies and scrutinise treatment and research licence applications. In order that a perspective can be maintained which is independent of the medical-scientific view, the HFE Act requires that the Chairman, Deputy Chairman and at least half of the HFEA's Membership may not be doctors or scientists involved in human embryo research or providing infertility treatment. Members are not appointed as representatives of different groups, but bring to the HFEA a broad range of expertise: medical; scientific; social; legal; managerial; religious; and philosophical.

The HFEA's Executive is responsible for implementing the HFEA's policy and licensing decisions and conducting the HFEA's day-to-day activities.

QUINQUENNIAL REVIEW

As an Authority established under an Act of Parliament (the Human Fertilisation and Embryology Act 1990), the HFEA is subject to Cabinet Office guidance governing reviews of Non-Departmental Public Bodies. The purpose of such reviews is to enable Ministers, Department of Health officials and the bodies themselves to review their performance and operation every five years.

The second quinquennial review of the HFEA was carried out during the spring and summer 2000. It consisted of a thorough examination of the Authority's operations and involved consultation with executive staff, members of the Authority, licensed centres, interested bodies and members of the public. The Minister approved the Quinquennial Review report in May 2001.

The main recommendations to come out of the review were that there was a continued need for an independent statutory body. There was no scope at present for merging the Authority with another body nor for contracting out the Authority's functions. At the same time, the reviewers recommended that the Authority should work towards having more open and transparent working practices. The HFEA welcomes this recommendation and is currently working towards developing policy in the area.

PERFORMANCE INDICATORS

The HFEA introduced Performance Indicators for the first time in April 1999 as a means of assessing the standards of its performance in various areas. Four headline indicators were chosen:

- PI 1 – Percentage of licence applications dealt with within target timescale;
- PI 2 – Percentage of requests for HFEA publications responded to within three days;
- PI 3 – Data entry unit costs per DI/IVF treatment;
- PI 4 – HFEA performance against Government financial targets including:
 - Percentage of creditors paid within 30 days;
 - Percentage of debts recovered within 60 and 90 days.

The HFEA's 2000/01 PI data are presented at Annex 6. The data show that the HFEA met most of its objectives. In areas where this was not the case, improvements have been made.

EFFICIENCY SAVINGS

The HFEA is committed to carrying out its duties to the highest standards whilst ensuring that costs are kept to a minimum. The HFEA made efficiency savings of approximately 3% in 2000/2001. Savings were achieved through the reorganisation of licensing team, management, the publication of the Annual Report in-house, carrying out the preparation work for the Patients' Guide in-house and making patient information available on the HFEA website.

THE CODE OF PRACTICE ON ENFORCEMENT

The HFEA's Code of Practice on Enforcement sets out the level of service that licensed clinics and the public can expect from the HFEA. Every licensed clinic has a copy of this document. It is also available on the HFEA's website (www.hfea.gov.uk).

THE REGISTER

The HFEA has a statutory duty to collect information about licensed treatments and their outcomes and maintains a register of information compiled from data provided by licensed clinics. Information is collected for the following main reasons:

- to provide information to children born as a result of such treatments;
- to monitor the provision of treatments; and
- to assist in the provision of information to the Government, patients, clinics and the general public.

The HFEA has responded to concerns that information taken from The Register, and published in The Patients' Guide to IVF Clinics and The Patients' Guide to DI, quickly becomes out of date and so does not represent the work of clinics adequately. To correct this, a new system for recording data has been developed that will allow information to be updated and made available more often.

In the course of developing this improved system, technical problems were identified with the quality of data for the period 2000-2001 and in the ease with which information could be retrieved to inform children born as a result of licensed treatments. These problems are being addressed, but resulted in a delay to the publication of The Patients' Guides for 2001. It is the intention of the HFEA to publish the data that would previously have been contained in these publications by August 2002.

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY 2000 – 2001

Chairman

Ruth Deech,

*Principal,
St Anne's College,
Oxford*

Deputy Chairman

Julia Tugendhat

Psychotherapist

Director of Committees

Jane Denton

*Director, The Multiple Births
Foundation, Queen Charlotte's &
Chelsea Hospital, London*

Members

Professor Brenda Almond

*Professor of Moral and Social Philosophy,
University of Hull*

Dr Sue Avery

Scientific Director, Bourn Hall Clinic

Professor Tom Baldwin

Professor of Philosophy, University of York

Professor David Barlow

*Nuffield Professor in Obstetrics and Gynaecology and
Head of Department, University of Oxford
Clinical Director, Assisted Reproduction Unit, John
Radcliffe Maternity Hospital, Oxford*

Ivor Brecker

*General Dental Practitioner, retired, Previously Dental
Reference Officer, Dental Practice Board.*

Professor Peter Braude

*Guy's, King's and St Thomas' School of Medicine, Head
of the Division of Women's and Children's Health*

Professor Iain Cameron

*Professor of Obstetrics and Gynaecology, University of
Southampton. Honorary Consultant in Obstetrics and
Gynaecology, Southampton University Hospitals NHS
Trust*

Professor Christine Gosden

*Professor of Medical Genetics, University of Liverpool,
Liverpool Women's Hospital*

Professor Andrew Grubb

*Professor of Medical Law, and Head of Department ,
Cardiff Law School, Cardiff University*

Simon Jenkins

Times Columnist

Professor Henry Leese

Professor of Biology, University of York

Professor Stuart Lewis

*Consultant Psychologist, Ulster Hospital & Community
Trust; Formerly, Professor of Psychology Applied to
Medicine, The Queen's University, Belfast*

Dr Anne McLaren

*Principal Research Associate, Wellcome CRC Institute,
Cambridge*

Dr Sadia Muhammed

General Practitioner, Priory Medical Group, York

Sara Nathan

*Freelance journalist, previously Editor of Channel 4
News*

The Right Reverend Dr Michael James Nazir-Ali

The Lord Bishop of Rochester

Sharmila Nebhrajani

Finance and Business Affairs Director, BBC New Media

Dr Francoise Shenfield

*Clinical lecturer in infertility RMU (UCH) and honorary
lecturer in medicine (ethics) (Dept of Medicine RF and
UCH Medical School)*

Jean Smith

*Specialist Social Worker in Adoption, Fostering and
Child Protection.*

Mrs Lis Woods

Previously, Commissioner HM Customs and Excise

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

Audit Committee

Lis Woods (Chair)
Andrew Grubb
Henry Leese
Sharmila Nebhrajani
Jean Smith

Code of Practice Committee

Jane Denton (Chair)
Sue Avery
David Barlow
Andrew Grubb
Anne McLaren
Sadiah Muhammed
Lis Woods

Communications Steering Group

Sadiah Muhammed (Chair)
Stuart Lewis
Sara Nathan
Jean Smith
Sharmila Nebhrajani

Ethics Committee

Bishop Michael (Chair)
Brenda Almond
Tom Baldwin
Christine Gosden
Andrew Grubb
Simon Jenkins
Henry Leese
Sara Nathan
Francoise Shenfield
Julia Tugendhat

Information Committee

Stuart Lewis (Chair)
Peter Braude
Sadiah Muhammed
Sara Nathan
Julia Tugendhat

Information Committee Co-opted Members

Karin Dawson
Clare Brown
Richard Fleming
Alison Murdoch

Licensing & Fees Committee

Julia Tugendhat (Chair)
Brenda Almond
David Barlow
Peter Braude
Iain Cameron
Jane Denton
Christine Gosden
Henry Leese
Stuart Lewis

Organisation & Finance Committee

Ruth Deech (Chair)
Jane Denton
Sharmila Nebhrajani
Julia Tugendhat
Lis Woods

Working Group on New Developments in Reproductive Technology

Anne McLaren (Chair)
Sue Avery
Peter Braude
David Barlow
Iain Cameron
Jane Denton
Christine Gosden
Henry Leese
Sara Nathan
Francoise Shenfield
Elaine Gadd (Observer)

Liz Woodeson acts as the Department of Health's observer at HFEA meetings

2. LICENSING AND AUDIT OF LICENSED CLINICS

INTRODUCTION

Every clinic in the UK that offers IVF or DI treatment, the storage of gametes (sperm or eggs) or embryos, or that carries out human embryo research, is required by law to be licensed by the HFEA. Licensed clinics are inspected annually. Not only does the licensing process ensure that proper standards are maintained, but also assists in informing the HFEA about current and developing practices. As such it is a useful mechanism for gathering and disseminating information and thereby helps to raise standards of practice. As of 31 August 2001 there were 120 clinics licensed to carry out various activities as shown in Table 1¹.

Table 1.

HFEA licensed clinics	
IVF and DI	76
IVF only	0
DI only	26
Storage of sperm only	12
Research licences only	6
Total	120

THE LICENSING AND INSPECTION PROCESS

All licensing decisions are made by HFEA Licence Committees. Each Committee is composed of five HFEA Members who determine whether a licence should be granted, suspended or revoked. If a licence is granted, centre-specific conditions may be attached.

Previously, licences were renewed annually. However, following a comprehensive review by the HFEA of its licensing system, the Authority agreed that established clinics could be issued with three-year licences. This recognised the fact that a large percentage of clinics have been licensed by the HFEA for many years, and that in most of these clinics compliance with the law and the Code of Practice is consistently very good.

A new clinic normally qualifies for a three-year licence only if it achieves good compliance during its first two years. Under the HFEA's three-year inspection cycle, each centre receives a broad-based general inspection by a full team once every three years, preceding its licence renewal. Smaller teams for interim or focussed inspections are identified by Licence Committees on a systematic basis according to the nature and licensing history of the clinics. This system means that the Authority can target its resources more effectively while reducing the burden of regulation on clinics as a whole.

1. A list of licensed clinics is at Annex 1.

The HFEA employs 58 part-time inspectors² who assist the HFEA in inspecting clinics. At full inspections the inspection team will normally consist of a clinician, a scientist, a person with a background in another field, such as counselling or nursing, as well as a member of the HFEA's Executive staff. Where an interim inspection is scheduled, a Licence Committee will determine the particular focus as well as the composition of the inspection team.

QUALITY SYSTEMS

The HFEA is committed to seek continual development in its regulation and licensing of clinics. As part of this development new inspection protocols have been incorporated into the inspection process. The protocols prompt inspectors to cover all relevant areas of compliance whilst encouraging wider discussion on general issues of good practice. The protocols are based on the requirements of the HFE Act, Code of Practice and relevant professional guidelines. The protocols are under regular review and development. Additionally inspections are placing increasing emphasis on examination of clinical and laboratory records in order to provide a detailed evidence base for inspection of compliance and best professional practice. During 2001 the HFEA has been further examining its licensing and inspection systems with regard to quality assurance and risk management. Developments to operational systems will be incorporated from late 2001.

BREACHES AND ENFORCEMENT

Information on alleged or apparent breaches of the HFE Act or the Code of Practice comes to the HFEA from a wide range of sources including HFEA inspections, information from patients, centre staff, analysis of the HFEA's database and from centres themselves.

Once information is received, preliminary investigations are carried out to determine whether there is *prima facie* evidence of a breach. Where this is the case, the HFEA will often seek specialist advice. All evidence and advice received is then submitted to a Licence Committee which decides whether any action should be taken. Where there is the possibility that a criminal offence may have been committed contrary to the HFE Act, a Licence Committee may decide to refer the matter to the Director of Public Prosecutions.

THE AUDIT PROGRAMME OF LICENSED CLINICS' DATA

The HFEA's five year Audit Programme of clinics data began on the 1st October 1996 and is currently in the fifth year of its five-year programme. The audit programme is used to monitor and improve the standard of the data held on its information register. The audit programme also provides assurance for the National Audit Office regarding the collection of licence fee income. The Comptroller and Auditor General has qualified his opinion to the Houses of Parliament on the 2000-2001 Accounts due to being unable to verify the completeness of licence fee income (see pages 50-51).

All licensed clinics are audited during the course of the programme. Feedback is given after every audit including a written report to which the clinic concerned may respond. This report is then considered by a Licence Committee which will direct any follow up action. The current programme will come to an end in the autumn of 2001; following a period of review the HFEA will embark on a new programme.

2 A list of HFEA Inspectors is at Annex 2.

3. The Code of Practice

INTRODUCTION

The HFE Act³ requires the HFEA to produce a Code of Practice to guide clinics on the standards they should establish in carrying out their licensed activities. It includes guidance on: egg sharing; the selection and screening of sperm donors; payment of expenses to donors; legal requirements for consent; handling and use of gametes and embryos; centre's staff and facilities; welfare of the child; and what information and counselling should be offered.

WELFARE OF THE CHILD

In particular, the Code of Practice provides guidance on the assessment of the welfare of the child. In passing the HFE Act Parliament decided that no category of women should be excluded from treatment. While the offer of treatment is a decision ultimately for the patient's clinician, the HFE Act requires every clinician to make this decision only after "account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth"⁴.

The Code of Practice provides guidance on how this assessment should be made. Clinics must bear in mind such factors as the prospective parents' ages and their likely future ability to look after, or provide for, a child's needs, and any risk of harm to the child or children who may be born. Where the child will have no legal father, clinics must pay particular attention to the prospective mother's ability to meet the child's needs throughout its childhood. Clinics must seek to satisfy themselves that the GP of each prospective parent knows of no reason why either of them should not be offered treatment – but they can only do this with their consent. Failure to give consent should be taken into account by the clinician in considering whether or not to offer treatment.

The HFEA does not usually become involved in individual decisions, but it is concerned to ensure that the necessary process is correctly followed and gives guidance on the decision-making process. A clinic's failure to follow the Code of Practice's guidance on the welfare of the child assessment would be a breach of the Code of Practice and would be considered by a Licence Committee.

THE FIFTH EDITION OF THE CODE OF PRACTICE

The Code undergoes regular revisions in the light of technical advances and to deal with issues that emerge from the licensing process. Revisions of the Code must be approved by the Secretary of State and laid before Parliament. The Code's second edition was published in June 1993, the third in December 1995, the fourth in July 1998 and the fifth in June 2001. The Code is available on the HFEA's website (www.hfea.gov.uk) and from the HFEA on request. Work has begun on the Code's sixth edition and it is anticipated that, subject to Ministerial approval, it will be published in Spring 2003. The next edition of the Code will include new guidance on the number of embryos that can be transferred per treatment cycle and access to confidential information by temporary staff.

3. HFE Act 1990 s.25

4. HFE Act 1990 s.13(5)

4. Research

INTRODUCTION

Research is vital for the advancement of clinical medicine. Early knowledge of human embryology was based entirely on the physical description of embryos at different stages of development and comparison with processes in other species, mainly the mouse. The first successful *in vitro* fertilisation of mouse ova was achieved in 1958 and was followed ten years later by the successful fertilisation of human eggs. With the ability to freeze and store embryos, the possibilities for research have risen significantly in the past few years.

Any research project involving the creation, keeping or using of human embryos outside the body must be licensed by the HFEA. To grant a research licence, the HFEA must be satisfied that the research is “necessary or desirable”, and that the use of human embryos is essential⁵. Before 2001 the HFEA could grant licences for research projects only for the following specified purposes⁶:

- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of congenital disease;
- increasing knowledge about the causes of miscarriages;
- developing more effective techniques of contraception; or
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

In January 2001 Parliament passed regulations extending the purposes for which research licenses may be authorised to include⁷:

- increasing knowledge about the development of embryos;
- increasing knowledge about serious disease;
- enabling any such knowledge to be applied in developing treatments for serious disease.

Human embryos obtained with appropriate consent for a research project may not be used for any other purpose. The following activities involving human embryos are not permitted under UK law:

- keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier;
- placing a human embryo in an animal;

5. HFE Act 1990 s.3(1)

6. HFE Act 1990 Schedule 2, para.3(2)

7. The HFEA are reviewing the current research licensing procedures in the light of the Parliamentary debate and will take into account the current House of Lords Select Committee's discussions before issuing further guidance.

- replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or a subsequent development of an embryo;
- altering the genetic structure of any cell while it forms part of an embryo; and using embryos for any other purposes except in pursuance of a licence.

It is also the HFEA's policy not to licence research projects involving embryo splitting with the intention of increasing the number of embryos for transfer⁸.

SECONDARY RESEARCH

Some embryos or embryo cells may be preserved or fixed (which renders the embryos non-viable) for future studies. Research on these embryos is called secondary research. Although the HFEA has no remit over the regulation of secondary research recent guidance produced by the HFEA recommends that patients should be informed of such research and the possible implications of this work, which could, for example, include genetic research.

In order to protect patient confidentiality it has been suggested that such embryos should be anonymised. Anonymisation can be reversible or irreversible. Where embryos are reversibly anonymised patients should be informed of the type of research to be carried out, and asked to consent to that research. Patients should be informed that some meaningful results may be fed back to them, and should be offered appropriate counselling about the implications of this. Where embryos are irreversibly anonymised patients should again be fully informed about the type of research involved, be asked to consent to the research, and be made aware of the inability to feed any results back to them.

LICENSED RESEARCH PROJECTS

As of 31st August 2001 the HFEA had received 135 applications for research licences since 1991. Of these, 115 were granted and work has been completed on 74 projects.

As of 31st August 2001 there were 28 licensed research projects ongoing at 18 different centres. Of these research projects, 24 are ongoing and four are new. A full list of the projects currently licensed by the HFEA can be found at Annex 3. The main objective of the majority of the projects currently licensed by the HFEA is to promote advances in the treatment of infertility.

THE RESEARCH LICENSING PROCESS

Approval by a properly constituted external Research Ethics Committee is a prerequisite for the HFEA to consider an application for a research licence. The HFEA's Code of Practice provides guidance on the use and constitution of such ethics committees⁹. An application for a research licence must contain a range of information on the proposed project including its objectives, protocols to be used and why the use of sperm, oocytes or embryos is necessary.

When an application for a research licence is received, it is sent out to Peer Review¹⁰. Peer Reviewers are asked to recommend whether the project should be licensed and to comment in particular on:

8. HFEA Code of Practice paragraph 10.5

9. HFEA Code of Practice para.10.8

10. A full list of the HFEA's Peer Reviewers can be found at Annex 4.

- whether the proposed research falls under the permitted purposes;
- the potential importance of the research to the particular field;
- whether the research has previously been undertaken elsewhere;
- whether the use of human embryos is justified in furthering knowledge in the field;
- the suitability of the methods to be used for achieving the stated aims of the research;
- the suitability of the proposed length of the study; and
- the suitability of the applicant's qualifications and professional background to undertaking research on human embryos.

Comments made by Peer Reviewers may be fed back to applicants to give them opportunity to clarify any issues raised before a Licence Committee considers whether a licence should be granted. The Licence Committee will consider the issues listed above as well as issues such as the information given to patients donating sperm, oocytes or embryos to the research project.

The HFEA inspects centres at which licensed research is carried out and requires reports to be submitted on the progress of projects. At the end of a research project the researchers are required to submit a final report containing the results and conclusions of the project and references to any publications resulting from the work.

5. Policy update and issues for the coming year

In addition to subjects covered elsewhere in this report, the HFEA is considering, or has recently considered, the following issues.

PREIMPLANTATION GENETIC DIAGNOSIS (PGD)

PGD is a technique used to detect whether an embryo created *in vitro* is carrying a genetic defect that will give rise to a serious inherited genetic disorder. It may also be used to determine the sex of an embryo where a family is at risk of passing on a serious sex-linked disorder, such as Duchenne's Muscular Dystrophy.

In August 2001 five centres were licensed to carry out PGD with one other centre licensed to carry out only the embryo biopsy procedure. PGD is currently practised on a small scale, but demand is expected to grow as knowledge about the genes responsible for different conditions increases and the techniques involved continue to develop.

The HFEA and the Advisory Committee on Genetic Testing (subsequently incorporated into the Human Genetics Commission (HGC)) issued a consultation paper on the issues surrounding the use of PGD at the end of 1999. In December 2000 a joint working party was formed involving Members of the HFEA and the HGC. The joint working party spent six months examining the arrangements for licensing PGD in the light of responses to the consultation and has formulated a number of recommendations for the development of policy in this area. A report on the consultation exercise, including the working party's recommendations, was published and is available on the HFEA and HGC websites (www.hfea.gov.uk and www.hgc.gov.uk).

CLONING AND STEM CELL RESEARCH

In 1998 the HFEA held a joint consultation with the Human Genetics Advisory Commission on human cloning. The resulting report distinguished between reproductive cloning and *in vitro* work using cell nucleus replacement technology with a therapeutic aim. The report recommended that while reproductive cloning should not be permitted, therapeutic cloning may hold promise for the treatment of serious illnesses.

Following the report of the Chief Medical Officer's Expert Group, which focussed on the possible therapeutic use of human embryonic stem cells, the Government laid regulations before Parliament in December 2000. These regulations, which came into force in January 2001, extend the purposes for which embryos may be used in research under licence, broadly along the lines recommended in the foregoing reports.

These additional purposes are:

- Increasing knowledge about the development of embryos;
- Increasing knowledge about serious disease, or
- Enabling any such knowledge to be applied in developing treatments for serious disease.

As the regulations came into force, a House of Lords Select Committee was simultaneously established to review

the consequences of implementing the regulations and the function of the HFEA in regulating this area. The Authority gave evidence to this committee and remains confident in its preparedness to process applications under the new regulations.

SCREENING FOR AGE-RELATED ANEUPLOIDY

Throughout 2001 the HFEA considered information relating to the preimplantation screening of embryos created *in vitro* for numerical chromosomal abnormalities (aneuploidy).

Screening is carried out either by testing cells removed from an embryo one or two days after fertilisation or by testing polar bodies which are discarded from the egg cell during its formation.

There is some evidence that IVF coupled with the use of this technique may improve the chances of achieving a successful outcome for certain categories of patient (such as older women and those with a history of miscarriage or IVF failure) although there remains a risk of misdiagnosis.

EMBRYO TRANSFER

The HFEA has long been concerned about the increase in multiple births as a result of infertility treatment. Multiple births are associated with premature birth, low birth weight babies, a higher rate of stillbirth and neonatal death and long term disability such as Cerebral Palsy. In addition to the health risks to the babies, there are also increased risks for the mother including complications at birth and stress and exhaustion due to coping with more than one baby.

In 2001 the HFEA reviewed its guidance regarding the number of eggs or embryos that can be transferred to a woman in any one treatment cycle. The HFEA recognises that there have been great advances in assisted reproductive techniques in the past decade resulting in improved success rates.

As a consequence the HFEA has amended its policy to state that no more than two embryos should be transferred in an IVF cycle except in exceptional circumstances, where a three embryo transfer may be performed. These exceptional circumstances, which may include clinical and laboratory criteria in a specific case, should be recorded in the patient records. This new policy aims to maintain pregnancy rates whilst greatly reducing the risk of triplet pregnancy.

EGG SHARING

Egg sharing is an arrangement whereby a woman may receive free or subsidised IVF treatment in return for donating her surplus eggs. The HFEA was persuaded that, if properly regulated and monitored, the practice could, in some cases, be beneficial to participants. The HFEA decided to allow egg sharing, but only on condition that strict HFEA guidance was followed to protect all those involved in such arrangements. Guidance for egg sharing was developed with the assistance of representatives from the British Fertility Society and the Royal College of Obstetricians and Gynaecologists. This guidance was issued to centres in September 2000 and was formalised in the fifth edition of the Code of Practice.

The guidance focussed on the content of the two separate agreements between the egg provider and the clinic, and the egg recipient and the clinic, and emphasised the need to discuss all possibilities and agree the course of action to be taken in advance of any treatment commencing. The guidance also requires centres to set a minimum number of eggs to be collected for sharing to take place. If, however, this minimum number is not reached the egg provider should be given the option to use all of her eggs for her treatment at no additional cost to herself and with no further commitment.

SCREENING OF SPERM DONORS

Following the publication of new guidelines by the British Andrology Society (BAS) the HFEA revised the Code of Practice on the screening of sperm donors. In line with the BAS, the HFEA has changed its policy with respect to the recruitment and use of cytomegalovirus (CMV) seropositive sperm donors. Wherever possible centres are required to recruit only CMV seronegative sperm donors. However, where a seropositive donor's sperm is used in treatment services it should only be to treat a seropositive recipient and information relating to the risks associated with CMV and pregnancy should be provided before any treatment is given.

STORAGE OF OVARIAN AND TESTICULAR TISSUE

The HFEA licenses the storage of sperm and eggs including ovarian and testicular tissue where mature gametes are, or might be, present – that is, testicular tissue where boys have reached puberty and ovarian tissue from girls or women where a mature egg may be present. The storage of ovarian and testicular tissue containing immature gametes comes under the Department of Health accreditation scheme for tissue banks in the United Kingdom. The Department of Health has now published a Code of Practice for Tissue Banks providing tissues of human origin for therapeutic purposes. This Code of Practice is based on current professional guidelines on tissue banking and was prepared in consultation with Royal Colleges and relevant professional organisations.

IN VITRO MATURATION OF EGGS

Following consultation with the Royal College of Obstetricians and Gynaecologists, the British Fertility Society and the Association of Clinical Embryologists the HFEA decided to allow the limited use of *in vitro* matured eggs in treatment. The HFEA recognised that this treatment could offer hope to women with polycystic ovary syndrome and women who have shown evidence of hyperstimulation in previous treatment. Approval was restricted to the *in vitro* maturation of immature oocytes from antral follicles in fresh cycles. The HFEA has insisted that clinics offering this treatment must inform patients of any risks involved and also give clear information about the success rate that is currently very low.

THE STATUTORY STORAGE PERIOD FOR GAMETES AND EMBRYOS

The statutory storage period for gametes and embryos is ten and five years respectively. The first ten year period for the storage of gametes since the 1990 Act's implementation ended on 1 August 2001. The HFEA has issued advice to centres explaining the impact of this deadline and what they need to do with those stored gametes that were reaching the end of their statutory storage period.

Under certain circumstances, gametes may be stored for more than ten years. The conditions allowing the storage period to be extended beyond ten years are detailed in the Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991.

SAFE CRYOPRESERVATION OF GAMETES AND EMBRYOS

In 1998 the HFEA established a Working Group on Safe Cryopreservation, which carried out a consultation exercise to try to establish what procedures could be introduced to reduce the risk of cross contamination between cryopreserved gametes and embryos.

Following the consultation exercise the working group was reconvened in 2000 to agree guidance for centres. A number of recommendations were proposed and were formalised in the fifth edition of the Code of Practice. The more technical recommendations were taken forward by the relevant professional organisations.

A further recommendation from the working group was that all patients should be screened before putting material into storage and, to this end, a questionnaire was sent to all centres to establish what impact this

requirement may have on their operation. Centres have now been asked to begin routine first-round screening for all patients wishing to store material and it is expected that this will be fully implemented by the end of 2004.

AGE LIMITS OF GAMETE PROVIDERS

As part of the HFEA's revision of their policy for the recruitment of sperm donors, it was agreed that the upper age limit should be lowered from 55 to 45 years, except in exceptional circumstances. This was in response to British Andrology Society guidelines, and other published papers, that had shown that children with older fathers were at a slightly higher risk of chromosomal abnormalities. This change in policy has been reflected in the fifth edition of the Code of Practice.

The upper age limit for egg donors of 35, except in exceptional circumstances, has remained unchanged.

SCREENING OF GAMETE AND EMBRYO DONORS

The Fifth Edition of the Code of Practice has clarified for centres the HFEA's policy on the screening of egg donors and embryo donors. The Code of Practice states that egg donors and the gamete providers that produced a donated embryo should be screened in the same way as is recommended for sperm donors. In addition, the British Fertility Society has published guidance on this issue.

WORKING GROUP ON NEW DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY

The Working Group on New Developments in Reproductive Technology (WGNDRT) advises the Authority on progress in, and the safety of, new clinical and scientific techniques that fall within the HFEA's remit. The WGNDRT also advises on the training standards for practitioners of techniques such as embryo biopsy, which is required for pre-implantation genetic diagnosis (PGD), and keeps newly licensed treatments under review.

In considering whether a new technique should be licensed by the HFEA, the WGNDRT explores:

- the biological basis of the procedure;
- evidence from animal research;
- evidence from human embryo research;
- evidence from clinical research; and
- evidence of expertise/competence of the practitioner.

Some issues that have been considered by the WGNDRT during the period of this report are summarised below.

THE USE OF DONOR GAMETES AND EVIDENCE OF INCREASED HYPERTENSIVE PROBLEMS IN PREGNANCY

The WGNDRT considered recently published papers that reported increases in hypertensive problems, including pre-eclampsia, in pregnancies resulting from donated gametes or embryos. It was noted that pre-eclampsia is a common problem, especially in first pregnancies. The WGNDRT therefore considered that the level of the problem was not sufficient to affect the provision of treatment using donor gametes and embryos. It did consider however, that patients having treatment using donated gametes or embryos should be made aware of the increased risk of hypertensive problems including pre-eclampsia, and that there should be general awareness of this issue among obstetricians.

THE USE OF POLAR BODY TESTING IN PRE-IMPLANTATION GENETIC DIAGNOSIS (PGD)

Polar bodies contain the half of the chromosomes ejected by the egg during its development. The WGNDRT considered both the reliability of testing polar bodies and whether the development of the egg was prejudiced following the procedure. The Group considered that polar body removal was safe but that practitioners should be

asked to demonstrate competency in the technique as are practitioners of embryo biopsy.

The WGNDRt considered that polar body testing would not always be a suitable technique for testing for single gene disorders, but would be a suitable technique to test for maternal age-related aneuploidy, dependent on the protocol.

The WGNDRt considered that protocols for the testing procedure should be proved to be reliable before a licence was granted.

SAFETY AND EFFICACY OF USING SPERM EXTRACTED FROM FROZEN AND THAWED TESTICULAR TISSUE

The WGNDRt considered the safety and efficacy of using sperm extracted from frozen and thawed testicular tissue. The WGNDRt noted that sperm are very stable and considered that although there may be concerns about the technique, they are not likely to be safety concerns. It was noted that various methodologies are in use in clinics, and the Group raised concerns that some appeared to be based on procedures for freezing embryo or ejaculated sperm, which may not be the most appropriate methods to use. The WGNDRt is reviewing the protocols in use and obtaining expert advice on their suitability.

6. Communications

The HFE Act requires the HFEA to “publicise the services provided to the public by the HFEA or provided in pursuance of licences” and to “provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos ... or may wish to do so.”¹¹ In fulfilling this function the HFEA offers a comprehensive range of information for current or prospective patients, donors and the general public (listed at the end of this chapter). The HFEA receive, on average, 250 requests per week for its publications. About twice a year the HFEA circulates a newsletter, ‘HFEA Update’, to licensed clinics and interested bodies, informing them of recent policy decisions and discussing areas of concern.

The HFEA works closely with journalists and media researchers and supplies speakers for national and international conferences and for press, radio and television interviews. In addition, HFEA Members and staff have written articles for mainstream, specialist and patient publications. The HFEA’s website (www.hfea.gov.uk) includes a range of information relevant to the public and professionals.

THE PATIENTS’ GUIDES TO DI AND IVF CLINICS

Since 1995 the HFEA has produced Patients’ Guides to DI and IVF Clinics to provide advice and information to people seeking infertility treatment. The Guides provide impartial advice and information about the many types of licensed treatment available, the issues to consider, and the live birth rates. This information will be available in future from the website at www.hfea.gov.uk.

THE HFEA ANNUAL CONFERENCE

The HFEA’s Annual Conference provides a forum for informed discussion and debate in the field of regulated fertility treatment. This one day conference gives the staff of licensed clinics, HFEA’s Members, Executive staff, Inspectors and other delegates an opportunity to discuss issues of mutual interest and to exchange views and ideas. The 2000 HFEA Annual Conference was held in London and was attended by more than 200 delegates. The Chairman of the Human Genetics Commission, Baroness Helena Kennedy, discussed the work of the Commission and Mr Kevin Artley and Mr Khaldoun Sharif discussed the egg sharing schemes in operation at their centres. There were also workshops on Human Rights, Egg Freezing, the Storage of Ovarian and Testicular Tissue and Patient Satisfaction.

REGIONAL AND OTHER MEETINGS

The HFEA recognises the importance of maintaining a continual dialogue with those involved, or interested in, the area of assisted reproduction. To facilitate this, the HFEA organised regional meetings in Liverpool and London. These meetings provided an opportunity for patients, nurses, clinicians, researchers and counsellors to meet with HFEA representatives to discuss HFEA policy.

¹¹ HFE Act 1990, section 8(c)

In addition, HFEA representatives have continued their regular meeting with the British Fertility Society, the Royal College of Obstetricians and Gynaecologists, the Association of Clinical Embryologists and the British Andrology Society. There is also ongoing contact with other organisations including the patient representative groups, CHILD and ISSUE, as well as the British Medical Association, the Family Planning Association, Progress, Donor Conception Network, the National Gamete Donation Trust, the Medical Research Council, the British Infertility Counselling Association, The Wellcome Trust, Pro-life groups and the Royal College of Nursing. The HFEA also works closely with the Department of Health on many areas of mutual concern.

INFORMATION AVAILABLE TO THE PUBLIC

The HFEA provides information that is available to prospective patients, interested organisations and the general public. Those requiring any of the following publications should contact the HFEA or the website www.hfea.gov.uk.

Annual Reports 1992-2001

The 1998 and 1999 Annual Reports are available from the Stationery Office price £10. The 2000 Annual Report is available from the HFEA office.

The Patients' Guides to DI and IVF Clinics

Pack Includes:

- The Patients' Guide to Infertility and IVF 2000
- The Patients' Guide to IVF Clinics 2000
- The Patients' Guide to DI 2000

The following lists are produced:

Centres that provide IVF with donor eggs
Sperm donor recruitment centres
PGD clinics
Egg freezing centres
Storage of sperm centres

Code of Practice Fifth Edition

Information Leaflets:

HFEA: Who we are and what we do
Egg Donation
Sperm and Egg Donors and the Law
Embryo storage
Welfare of the Child: Information for GPs
Welfare of the Child: Information for Patients
Intra Cytoplasmic Sperm Injection (ICSI): Information for Patients
Storage and Use of Frozen Eggs
Consent to the Use and Storage of Gametes and Embryos

Website:

<http://www.hfea.gov.uk>

ANNEX 1 LICENSED CLINICS

(as of 31 August 2001)

Avon

Centre for Reproductive Medicine,
Bristol University
Royal United Hospital, Bath
Southmead General Hospital, Bristol
St Michael's Hospital, Bristol
Tower House Clinic, Bristol
University of Bristol IVF Service, The
BUPA Hospital, Bristol

Buckinghamshire

BMI Chiltern Hospital, Great
Missenden
Thames Valley Nuffield Hospital
Cambridgeshire
Bourn Hall Clinic, Bourn
Peterborough District Hospital
Rosie Maternity Hospital,
Cambridge

Cleveland

Cleveland Fertility Centre, Stokesley
Hartlepool General Hospital
South Cleveland Hospital,
Middlesbrough

Derbyshire

Derby City General Hospital

Devon

Derriford Hospital, Plymouth
Heavitree Hospital, Exeter

Dorset

Winterbourne Hospital, Dorchester

Durham

Bishop Auckland General Hospital

East Sussex

Esperance Private Hospital,
Eastbourne

Essex

Brentwood Fertility Centre
Essex Fertility Centre, Buckhurst Hill
North East London Fertility Services,
Ilford
The Oaks Hospital, Colchester

Greater Manchester

Billinge Hospital, Wigan
Centres for Assisted Reproduction
Ltd. (CARE) at the Alexandra
Victoria Park Hospital,
Manchester
Manchester Fertility Services, BUPA
Manchester Hospital
Regional IVF & DI Unit, St Mary's
Hospital, Manchester
Salford Royal IVF and Fertility
Centre, Hope Hospital, Salford

Hampshire

BUPA Chalybeate Hospital,
Southampton
North Hampshire Fertility Centre,
North Hampshire Hospital,
Basingstoke
The Hampshire Clinic, Basingstoke
Wessex Fertility Services, Princess
Ann Hospital, Southampton

Herfordshire

Watford General Hospital

Humberside

Princess Royal Hospital, Hull

Kent

BMI The Chaucer Hospital,
Canterbury
BMI Chelsfield Park Hospital
Queen Mary's Hospital, Sidcup
Maidstone fertility centre

Leicestershire

Leicester Royal Infirmary
Middle England Fertility Centre,
BUPA Hospital, Leicester

London

Assisted Conception Unit, University
College Hospital
Assisted Reproduction and
Gynaecology Centre
Chelsea & Westminster Hospital
Cromwell Hospital
Dr Louis Hughes
Fertility Unit, The Portland Hospital
London Fertility Centre
London Women's Clinic/Hallam
Medical Centre
London Women's Clinic, The
Portland Hospital
Reproductive Medicine Unit,
University College Hospital
Seymour Clinic, St Mary's Hospital
St Bartholomew's Hospital
St Thomas' Hospital
The Bridge Centre
The Harley Street Fertility Centre
The Harley Street Clinic
The Lister Hospital

London (East)

Homerton Hospital
Newham General Hospital

London (North)

London Female and Male Fertility
Centre, Highgate Private
Hospital

London (South)

Diana, Princess of Wales Centre for
Reproductive Medicine, St
George's Hospital, Tooting
King's College Hospital

London (West)

West Middlesex University Hospital
Wolfson Family Clinic,
Hammersmith Hospital

Merseyside

BUPA Murrayfield Hospital, Wirral
Liverpool Women's Hospital
University Hospital Aintree,
Liverpool

Northern Ireland

Royal Maternity Hospital, Belfast

Norfolk

James Paget Healthcare NHS Trust,
Great Yarmouth

Northamptonshire

BMI Three Shires Hospital,
Cliftonville
Centres for Assisted Reproduction
Ltd. (CARE) at the Park Hospital,
Arnold
NURTURE, University of Nottingham
Queen's Medical Centre,
Nottingham

Oxfordshire

John Radcliffe Maternity Hospital,
Oxford

Scotland – Grampian

University of Aberdeen

Scotland – Lothian

Royal Infirmary of Edinburgh
Western General Hospital,
Edinburgh

Scotland – Orkney

Balfour Hospital, Orkney

Scotland – Strathclyde

BMI Ross Hall Hospital, Glasgow
Glasgow Nuffield Hospital
Glasgow Royal Infirmary
Monklands Hospital Acute NHS
Trust, Airdrie

Scotland – Tayside

Ninewells Hospital and Medical
School, Dundee

Shropshire

Shropshire and Mid-Wales Fertility
Centre, Royal Shrewsbury
Hospital

Staffordshire

North Staffordshire Nuffield
Hospital, Newcastle-under-Lyme
Queen's Hospital, Burton-upon-
Trent

Surrey

Shirley Oaks Hospital, Croydon
Woking Nuffield Hospital

Tyne and Wear

Cromwell IVF & Fertility Centre, The
BUPA Washington Hospital
Queen Elizabeth Hospital,
Gateshead
Sunderland Royal Hospital
The International Centre for Life,
Newcastle-upon-Tyne

Wales (South Glamorgan)

BUPA Hospital Cardiff
University Hospital of Wales, Cardiff

Wales (West Glamorgan)

Cromwell IVF and Fertility Centre,
Singleton Hospital, Swansea
Neath General Hospital

West Midlands

Birmingham Women's Hospital
BMI Priory Hospital, Birmingham
Midland Fertility Services, Aldridge
New Cross Hospital,
Wolverhampton
Walsgrave Hospital, Coventry

Yorkshire (South)

Sheffield Fertility Centre

Yorkshire (West)

Clarendon Wing, Leeds General
Infirmary
St James' University Hospital Leeds

CLINICS WITH STORAGE LICENCES ONLY

Andrology Unit, Hammersmith
Hospital
Bridge Centre Cryoservices, London
Cheltenham General Hospital
Christie Hospital NHS Trust
North West Wales Fertility Centre,
Gwynedd Hospital, Bangor
Royal Surrey County Hospital,
Guildford
Singleton Hospital, Swansea
Yorkshire Regional Tissue Bank,
Wakefield
Andrology Unit, Royal Hallamshire
Hospital, Maidstone Hospital
New Cross, Wolverhampton

ANNEX 2 INSPECTORS

(as of 31 August 2001)

CLINICIANS

Mr Masoud Afnan

*Consultant Obstetrician & Gynaecologist,
Honorary Senior Lecturer
Director of ACU, Birmingham
Maternity Hospital*

Mr Peter Brinsden

*Medical Director, Bourn Hall
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Cambridge*

Mr Chris Chandler

*Clinical Director, Consultant
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Billinge Hospital, Wigan*

Dr Ruth Curson

*Associate Specialist, King's
College Hospital, London*

Mr Robert Forman

*Medical Director, Centre for
Reproductive Medicine, London*

Professor Stephen Franks

*Professor of Reproductive
Endocrinology, St Mary's
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Dr Mark Hamilton

*Consultant Obstetrician & Gynaecologist,
Clinical Senior Lecturer,
University of Aberdeen*

Mr Richard Kennedy

*Consultant Obstetrician & Gynaecologist,
Walsgrave Hospital, Coventry*

Mr Charles Kingsland

*Consultant Obstetrician & Gynaecologist, Honorary Lecturer,
The Women's Hospital Liverpool*

Dr Martin Lees

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Dr John Mills

*Consultant Obstetrician & Gynaecologist,
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Dr Alison Murdoch

*Consultant Obstetrician & Gynaecologist,
Honorary Senior Lecturer,
Director of the Centre for
Reproductive Medicine,
International Centre for Life,
Newcastle upon Tyne*

Mr Roger Neuberg

*Consultant Obstetrician & Gynaecologist, Director of
Infertility Service, Leicester
Royal Infirmary,
Co-Director of BUPA Leicester*

Mr Julian Pampiglione

*Consultant Obstetrician & Gynaecologist, The Royal
Bournemouth Hospital*

Mr John Parsons

*Senior Lecturer
Honorary Consultant, King's
College Hospital, London*

Dr Elizabeth Pease

*Consultant, St Mary's Hospital,
Manchester*

Dr David Polson

*Consultant in Obstetrics & Gynaecology,
Salford Royal IVF & Fertility Centre*

Mr Anthony Rutherford

*Consultant Obstetrician & Gynaecologist,
The Leeds Teaching Hospitals
NHS Trust*

Mr Robert Sawers

*Consultant Obstetrician & Gynaecologist,
Programme Director, BMI Priory
Hospital, Birmingham*

Mr Eric Simons

*Medical Director,
Cromwell Hospital, London*

Dr Alison Taylor

*Consultant,
Senior Lecturer, Guy's and
St Thomas' Hospital, London*

Mr Peter Wardle

*Consultant & Senior
Lecturer in Obstetrics & Gynaecology, Southmead
Hospital, Bristol*

Dr Christine West

*Consultant Obstetrician & Gynaecologist,
Royal Infirmary, Edinburgh*

Dr Robin Yates

*Medical Research Director,
Assisted Conception Unit, Royal
Infirmary, Glasgow*

SCIENTISTS

Dr Linda Baggott
*Lecturer in Biology and Education,
University of Exeter*

Dr Virginia Bolton
*Senior Lecturer,
King's College Hospital, London*

Dr John Clarke
*Retired Lecturer in Zoology,
University of Oxford*

Dr John Coutts
Retired Reader in Reproductive Endocrinology

Ms Karin Dawson
*Consultant Embryologist,
Hammersmith Hospital, London*

Dr Simon Fishel
*Managing Director,
Centres for Assisted Reproduction Ltd. (CARE), Park Hospital,
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Professor Tom Fleming
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King's College, London*

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University Department of Obstetrics & Gynaecology,
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Edinburgh Assisted Conception Unit*

Mr Terry Leonard
*Co-Director, ISIS Fertility Centre,
Colchester*

Dr Alan McDermott
Director, Regional Cytogenetics

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Dr Dave Morroll
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NURTURE, Nottingham*

Ms Barbara Ray
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Centre for Reproductive Medicine, Bristol*

Dr John Robinson
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Reverend Professor Mary Seller
*Professor of Development Genetics,
Medical & Molecular Genetics,
Guy's Hospital, London*

Dr Arasaratnam Srikantharajah
*Research Embryologist,
University of Aberdeen*

Mr Stephen Troup
*Scientific Director,
Liverpool Women's Hospital*

Dr Karen Turner
*Senior Clinical Embryologist,
Queen's Hospital, Burton-on-Trent*

Reverend Professor Paul Watson
*Professor of Reproductive Cryobiology,
Royal Veterinary College, London*

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SOCIAL AND ETHICAL INSPECTORS

Mrs Sarah Biggs
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Committee on Counselling,
London*

Mrs Linda Breeze
*Relate
Psychosexual Therapist and*

*Fertility Counsellor at Royal Devon
and Exeter Hospital*

Ms Jennifer Clifford
Counsellor

Mrs Elizabeth Corrigan
*Nursing Director,
St Michael's and BUPA Hospital,
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*Teaching fellow in social work,
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*Lecturer,
SCHARR, University of Sheffield*

Mrs Roz Shaw-Smith
*Counselling Psychologist,
John Radcliffe Hospital, Oxford*

Ms Jennifer Speirs
*Freelance Infertility Counsellor
and Social Work Consultant,
Edinburgh*

ANNEX 3 RESEARCH PROJECTS

(as of 31 August 2001)

Bourn Hall Clinic

Oocyte preservation

Centre for Genome Research, University of Edinburgh

Culture of multipotential human embryo cells

Glasgow Royal Infirmary

Detection of autosome and sex chromosome abnormalities in human pre-implantation embryos using FISH and the PCR

Clarendon Wing – Leeds

Diagnosis of trisomies and DNA fingerprinting in human blastomeres to improve pre-implantation genetic diagnosis

Maturation and fertilisation of human eggs *in vitro*

Study of human eggs matured *in vitro* and *in vivo*

Segregation of mitochondrial DNA (MTDNA) in human embryos

Guy's and St Thomas' Hospital, London

Improving methods for the biopsy and diagnosis of inherited genetic disease of human pre-implantation embryos

The Hammersmith Hospital, London

Pre-implantation genetic diagnosis – parallel investigations

To measure the activity of enzymes implicated in genetic disorders

To measure the activity of metabolic enzymes in spare human pre-implantation embryos

International Centre for Life, Newcastle

An investigation of the use of laser biopsied blastocytes for pre-implantation diagnosis

Isolation and characterisation of cell lines from human

pre-implantation embryos.

Study of the involvement of the cellular stress response in the cause of embryo attrition and developmental defects in the human using human embryonic stem cells.

Jessop Hospital

An investigation of embryonic-endometrial dialogue during the peri-implantation period *in vitro* (with Sheffield Fertility Centre)

King's College Hospital London, School of Biomedical Sciences

The effect of fertilisation promoting peptide, calcitonin and angiotensin II on the stimulation of human sperm penetration of zona-free hamster oocytes

Liverpool Women's Hospital

Biopsy practice of three pronucleate embryos

Manchester Fertility Services

In vitro development and implantation of normal human pre-embryos and comparison with uni- or poly-nucleate pre-embryos (with St Mary's Hospital, Manchester and University of Manchester)

Oxford Fertility Unit

Segregation of mitochondrial DNA in human embryos (with Walsgrave Hospital)

Development of a model to study implantation in the human

Royal Infirmary of Edinburgh

Cell biology of human spermatozoa

Royal Hallamshire Hospital, Dept of Molecular Biology and Biotechnology

An investigation of embryonic-endometrial dialogue

during the peri-implantation period *in vitro* (with Jessop Hospital)

Royal Victoria Infirmary , Newcastle

Expression of trophinin, tastin and bystin complex in embryo-endometrial interaction. An *in vitro* experimental study.

St Mary's Hospital, Manchester

In vitro development and implantation of normal human pre-embryos and comparison with uni- or polynucleate pre-embryos (with Manchester Fertility Services and University of Manchester)

University College Hospital, London

The development of novel PGD procedures and the study of early human development

University of Aberdeen

Metabolism of human embryos as an index of quality

University of Manchester

In vitro development and implantation of normal human pre-embryos and comparison with uni- or polynucleate pre-embryos (with Manchester Fertility Services and St Mary's Hospital)

University of York

Biochemistry of early human embryos

Walsgrave Hospital, Coventry

A study of the effects of cell death on the further development of human embryos *in vitro*

In vitro maturation and fertilisation of oocytes from women with polycystic ovarian disease

Segregation of mitochondrial DNA in human embryos (with Oxford Fertility Unit)

In vitro maturation and fertilisation of immature oocytes from women under going ICSI treatment

Randomised controlled clinical trial of blastocytes vs. cleaving embryo transfer

ANNEX 4 PEER REVIEWERS

Professor Jonathan Aitken
Head of Department of Biological Sciences, University of Newcastle, New South Wales, Australia

Dr Gulam Bahadur
Clinical Biochemist, Head of Fertility Laboratories, University College London Medical School/University College, London Hospital Trust

Mr Adam Balen
Consultant Obstetrician & Gynaecologist and Sub-specialist in Reproductive Medicine, Leeds General Infirmary

Professor David Barlow
Nuffield Professor of Obstetrics & Gynaecology, University of Oxford, Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital, Oxford

Dr Siladitya Bhattacharya
Lecturer in Obstetrics & Gynaecology, University of Aberdeen

Dr Virginia Bolton
Senior Lecturer, King's Assisted Conception Unit

Professor Peter Braude
Head of the Division of Women's and Children's Health, Guy's, Kings and St Thomas' School of Medicine,

Professor Nigel A Brown
Professor of Developmental Biology, Department of Anatomy and Developmental Biology, St George's Hospital Medical School, London

Professor Iain Cameron
Professor of Obstetrics and Gynaecology, University of Southampton, Honorary Consultant in Obstetrics and Gynaecology, Southampton University Hospitals NHS Trust

Dr John Carroll
Department of Anatomy & Developmental Biology, University College, London

Dr J R T Coutts
Retired Reader, Division of Biochemistry and Molecular Biology, University of Glasgow

Professor Mark Curry
Senior Lecturer in Equine Science, Department of Agriculture and Horticulture, De Montford University

Ms Karin Dawson
Consultant Embryologist, Hammersmith Hospital, London

Professor Joy Delhanty
Professor of Human Genetics, University College, London

Dr Simon Fishel
Managing Director, CARE at the Park Hospital, Arnold, Nottingham

Dr Richard Fleming
Department of Obstetrics & Gynaecology, Glasgow Royal Infirmary

Professor Stephen Franks
Professor of Reproductive Endocrinology, St Mary's Hospital Medical School, London

Professor Lynn Fraser
Professor of Reproductive Biology, King's College, London

Dr Rafet Gazvani
Lecturer in Obstetrics & Gynaecology, University of Aberdeen

Professor Christine Gosden
Professor of Medical Genetics, University of Liverpool, Liverpool Women's Hospital

Professor Roger Gosden
Professor of Reproductive Biology, University of Leeds

Dr Mark Hamilton
Clinical Science Lecturer, Department of Obstetrics & Gynaecology, University of Aberdeen

Dr Joyce Harper
University College London

Dr Geraldine Hartshorne
*Scientific Director, Walsgrave
Hospital Assisted Conception
Unit, Coventry, Principal Research
Fellow, Department of Biological
Sciences, University of Warwick*

Professor Alan Handyside
*School of Biochemistry and
Molecular Biology, University of
Leeds*

Mr Jonathan Hewitt
*Consultant Obstetrician &
Gynaecologist, Chairman of
Medical Committee, Liverpool
Women's Hospital*

Dr Mark Johnson
*Senior Lecturer in Obstetrics,
Chelsea & Westminster Hospital*

Professor Martin Johnson
*Professor of Reproductive
Sciences, University of Cambridge*

Professor M H Kaufman
*Professor of Anatomy, University
of Edinburgh*

Dr Sue Kimber
*Senior Lecturer, University of
Manchester*

Mr Charles Kingsland
*Consultant in Obstetrics &
Gynaecology, Liverpool Women's
Hospital*

Professor G E Lamming
*Department of Physiology and
Environmental Science, University
of Nottingham*

Professor Henry Leese
*Department of Biology, University
of York*

Dr Brian Lieberman
*Medical Director, Regional IVF
and DI Unit, St Mary's Hospital,
Manchester*

Dr Alan McDermott
*Director, Regional Cytogenetics
Centre, Southmead Hospital,
Bristol*

Dr Anne McLaren
*Principal Research Associate,
Wellcome/CRC Institute,
Cambridge*

Professor Alan McNeilly
*Deputy Director and Senior
Scientist, MRC Reproductive
Biology Unit, Edinburgh*

Dr Tony Michael
*Lecturer in Biochemistry,
Department of Biochemistry &
Molecular Biology, Royal Free &
University College Medical
School, London*

Professor Marilyn Monk
*Head of Molecular Embryology
Unit, Institute of Child Health,
London*

Professor R Moor
Babraham Institute, Cambridge

Professor H D M Moore
*Professor of Reproductive Biology,
Department of Molecular Biology
and Biotechnology, University of
Sheffield*

Professor David Pegg
*Director, Medical Cryobiology
Unit, Biology Department,
University of York*

Dr Ian Sargent
John Radcliffe Hospital, Oxford

Dr Karl Swann
*Reader in Cell Physiology,
University College, London*

Professor Allan Templeton
*Professor of Obstetrics &
Gynaecology, University of
Aberdeen*

Reverend Professor Paul Watson
*Professor of Reproductive
Cryobiology, Royal Veterinary
College, London*

Professor Robert Webb
*Professor of Animal Production,
Department of Agriculture and
Horticulture, University of
Nottingham*

Dr Maureen Wood
*Research Fellow, Department of
Anatomy and Developmental
Biology, St George's Hospital
Medical School, London*

Professor Michael Whitaker
*Head of Department, Department
of Physiological Sciences,
University of Newcastle*

Professor David Whittingham
*Emeritus Professor of
Experimental Embryology,
St George's Hospital Medical
School*

ANNEX 5 LIST OF MEMBERS' INTERESTS

Ruth Deech (Chairman)

Principal, St Anne's College, Oxford

- Shares in Glaxo (through a PEP) and Oxford Glycobiology
- Member – United Oxford & Cambridge Club; Royal Society of Medicine
- St Anne's College has shares in London International GP, Glaxo, Smithkline Beecham, Zeneca GP, Nyomed Amersham
- Rolls Royce – Supports engineering at St Anne's College
- Linnells Solicitors (Dr John Deech, Partner)

Julia Tugendhat (Deputy Chairman)

Psychotherapist in Private Practice

- Vice President: British Association of Counselling
- Shares in Abbey National, CGNU, Diageo PLC, Hill Samuel British Trust, Royal Sun Alliance, Unilever PLC, Vodafone, Pearson, British Telecom, Sainsbury, Glaxo Smith Kline, Scottish Power, M&G recovery Fund, M&G Investment Trust, Merrill Lynch Balanced Portfolio, Murray Extra Return Investment Trust and various fixed interest securities.

Jane Denton (Director of Committees)

Director, The Multiple Births Foundation, Queen Charlotte's & Chelsea Hospital, London

- Editorial Board Member, Human Fertility
- The MBF receives grants from the Gatsby Charitable Foundation, Smiths Charity,
- Member of: Royal College of Nursing Fertility Nurses Group, British Fertility Society, British Infertility Counselling Association.

Sue Avery

Scientific Director, Bourn Hall

- Committee Member of Association of Clinical Embryologists

- Committee Member of British Fertility Society
- Bourn Hall is owned by Serono Pharmaceuticals
- Occasional consultancy work for Wallace Womens Health Care

Brenda Almond

Professor of Moral and Social Philosophy, University of Hull

Tom Baldwin

Professor of Philosophy, University of York

- Member of Nuffield Council on Bioethics
- Personal shares in Glaxo-Wellcome and SmithKline Beecham

David Barlow

Nuffield Professor of Obstetrics and Gynaecology and Head of Department, University of Oxford. Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital, Oxford.

- Consultancy with Pharmaceutical Industry: Novo-Nordisk
- Intermittent involvement with advisory committees and expert reports for pharmaceutical industry: Novo-Nordisk; Ely Lilly; Servier; Pharmacia
- Directorship of Oxford Reproductive Biosystems
- Board or Council positions on public organisations (unpaid): RCOG; National Osteoporosis Society; British Menopause Society;
- Editor in Chief of scientific journal "Human Reproduction" published by Oxford University Press
- Membership of research assessment bodies: HEFCE RAE2001 Panel Member, South East Region NHS R7D committee (Chairman) Department receives research grants from many sources (no personal gain): The Wellcome Trust; Action Research; WellBeing; MRC; EU; OXAGEN; NHS R&D

Programme; Schering; Searle; Serono; Organon; Zeneca; Wyeth; Jansen-Cilag; Pharmacia-Leiras

Peter Braude

Guy's, Kings and St Thomas' School of Medicine, Head of the Division of Women's and Children's Health

- Intermittent involvement and expert advisor to Serono Pharmaceuticals, Ares Serono, Tommy's Campaign, Wellbeing and PPP
- Personal shares in: Marks & Spencer, Centrica
- Dept. holds grants from Tommy's Campaign, MRC, BHF, Organon, Ares Serono, Serono Pharmaceuticals UK, Welch Allen, Sir Jules Thorn Trust, Zeneca
- Intermittent writing/editing Mosby, Harcourt-Brace, RCOG, OUP

Ivor Brecker

General Dental Practitioner, retired.

- Previously Dental Reference Officer, Dental Practice Board.
- Medico-legal consultancy for community health councils (voluntary), dentists and solicitors.
- Personal shares in Glaxo-Wellcome, Abbey National, Bradford and Bingley

Iain Cameron

Professor of Obstetrics and Gynaecology, University of Southampton, Honorary Consultant in Obstetrics and Gynaecology, Southampton University Hospitals NHS Trust

- Consultancy with pharmaceutical industry: Leiras, Takeda
- Editor-in-Chief, Reproductive Medicine Review (Cambridge University Press)
- Publishing/lecturing for various organisations
- Royal College of Obstetricians and Gynaecologists (Convenor of Postgraduate Meetings and Chairman, Meetings Committee)
- Specialist Advisor (Menorrhagia), NICE
- MRC Advisory Board
- Scientific Committee, National Endometriosis Society (no personal gain)
- Current research grants from the MRC, the Wessex Medical Trust and the Solent Subfertility Trust (no personal gain)
- Current membership of learned societies: Society for the Study of Fertility, Blair Bell Research Society

(Chariman), British Fertility Society, American Society for Reproductive Medicine, Endocrine Society, Society for the Study of Reproduction, Society for Gynecological Investigation, Society for Endocrinology.

Christine Gosden

Professor of Medical Genetics, University of Liverpool, Liverpool Women's Hospital

Honorary Consultant, Liverpool Women's Hospital, NHS Trust

- Intermittent writing/publishing: Oxford University Press, Blackwells, Churchill Livingstone, Wiley Saunders, Times Higher Education Supplement, Washington Post
- Commissions for filming/interviews/articles, CBS, Channel 4
- Holder of research grants; Wellbeing, North West Cancer Research Fund, Roy Castle International Foundation for lung cancer research, NHS NW R&D Research funding, Humanitas, UK Department for International Development, US State Department
- Fees received for lectures on cancer, fetal medicine, human rights, genocide
- Small personal shareholdings; Abbey National, Scottish Power

Andrew Grubb

Professor of Medical Law and Head of Department, Cardiff Law School, Cardiff University

- Various author and editorial royalties from academic publishers
- Part time Immigration Adjudicator, Immigration Appellate Authority
- Barrister

Simon Jenkins

Times Columnist

Henry Leese

Professor of Biology, University of York

Director and shareholder in Cellutions Ltd, a company that will develop embryo culture media (part funded by a grant from DTI and Medi-Cult)

- Research grants from: Medical Research Council (no personal gain)
- Editor in Chief, Human Fertility

- Committee Member: British Fertility Society
- Shareholdings in: Allied Domecq, Astra Zeneca, Barclays, Bass, Compass Group Granada, ICI, M&G, Prudential, Reed International, Royal Bank of Scotland, Save & Prosper, Syngenta

Stuart Lewis

Consultant Psychologist, Ulster Hospital & Community Trust; Formerly, Professor of Psychology applied to Medicine, The Queen's University, Belfast.

- Sessional Consultant at Ulster Community and Hospital Trust

Anne McLaren

Principal Research Associate, Wellcome/CRC Institute, Cambridge

- Member of Progress Educational Trust, Society for Reproduction and Fertility, British Society of Developmental Biology, European Society for Human Reproduction and Embryology and Genetical Society
- Trustee of British Fertility Society, Novartis Foundation and Oxford International Biomedical Centre
- European Developmental Biology Organisation (President)
- Royal Society (Fellow)
- Royal College of Obstetrics & Gynaecology (Fellow)
- Project Grant Holder from Wellcome Trust (including post-retirement stipend)

Sadia Muhammed

General Practitioner, Priory Medical Group, York

- Forensic medical examiner on retained and fee basis, North Yorkshire Police
- Member of North Yorkshire Health Authority Expert Sub-Fertility Group

Sara Nathan

Freelance journalist, previously Editor of Channel 4 News

- Freelance journalism for a range of publications
- Shareholdings in Williams, Rio Tinto, Shell, Imperial Chemical, Cookson Group, Diageo, Glaxo Wellcome
- Council Member, Jewish Museum
- Member of Radio Authority

- Lay Member, Professional Conduct Committee of the Bar Council
- Assorted Broadcasting Consultancies
- Member of Criminal Injuries Compensation Appeals Panel
- Chair, Lambeth's Children First Commission
- Member, Home Office Gambling Review Body
- Marshall Commissioner

Michael Nazir-Ali

Lord Bishop of Rochester

Director, Diocesan Board of Finance

President, Diocesan Board of Education

- Harper Collins; SPCK; Paternoster; Publishers of books & Regnum Kingsway
- Fellow, St Edmund Hall, Oxford University
- Endowed lectureships; University of Cambridge; University of Oxford; Queen's Belfast; Wycliffe College, Toronto; St John's, Auckland, NZ
- Visiting Professor, Faculty of Humanities, University of Greenwich
- Chairman of Council, Trinity College, Bristol
- Company Director, Central Board of Finance of the Church of England
- Trustee, Christian Weekly Newspaper

Sharmila Nebhrajani

Finance & Business Affairs Director, BBC New Media & Technology

- Special Advisor, Prime Minister's Delivery Unit
- KPMG (Husband, Peter Wallace, is an Executive Consultant)

Francoise Shenfield

Clinical lecturer in infertility RMU (UCH) and honorary lecturer in medicine (ethics) (dept of Medicine RF and UCH medical School)

- Progress Educational Trust Board Member
- Member of the Scientific Committee of "La Revue du Practicien-Gynecologie et Obstetrique"
- Lecturer on Ethics for the International Academic Advisory Board of the Austrian Danube University of Krems
- Co-ordinator of the Special Interest Group of Ethics and Law for the European Society for Human Reproduction and Embryology, and of its Ethics Taskforce

- Member of Editorial board of Journal of International Society of Bioethics SIBA
- Lecturer on Ethics for Sero Symposia USA at Bourn Hall

Jean Smith

Specialist Social Worker in Adoption, Fostering and Child Protection.

- Retired Head of Social Work Dept, Hull Maternity Hospital
- Director, Linnaeus House Family Assessment Unit, Hull
- Committee Member, Family Conciliation Service, Hull
- Lay Member/V. Chair, Yorkshire Wolds and Coast Primary Care Group

Lis Woods

Formerly, Commissioner HM Customs and Excise

- Occasional management consultancy projects for Department of Health and others

ANNEX 6 DETAILS OF PERFORMANCE INDICATORS

1. Percentage of licence applications dealt with within target timescale

ii) New treatment licences

Month	No of applications received	No of applications processed within timescale
April 2000 – March 2001	1	1

Summary: The data above indicates that the Authority dealt with the only application on time.

ii) Renewal

Month	No of applications received	No of applications processed within timescale
April 2000 – March 2001	54	42

Summary: During the period 54 applications for licence renewal were received. Of these, 12 of these were delayed and missed the target date mostly caused by delays within the HFEA. The overall target was set at 90%, but only 78% were dealt with on time. The licensing team suffered a high turnover of staff during the year and four new inspector co-ordinators were trained. This affected the ability to meet the target dates. During the latter stages of the year the figures improved, as did the management of the licensing process.

iii) Research – New applications

Month	No of applications received	No of applications processed within timescale
April 2000 – March 2001	2	2

Summary: The data above indicates that the Authority dealt with the two applications on time.

iv) Research Renewal applications

Month	No of applications received	No of applications processed within timescale
April 2000 – March 2001	19	11

Summary: The target of 90% was not reached as only 58% of applications were dealt with on time, but the missed applications were mostly beyond the HFEA's control.

v) Number of variations granted

Month	No of applications received	No of applications processed within timescale
April 1999 – March 2000	75	74

Summary: 98% of all applications were dealt with on time against the agreed target of 90%

2. Percentage of requests for HFEA publications responded to within three days

Month	Average % of publications dealt with within 3 days
April 200 – March 2001	80%

Summary: This data shows that generally the HFEA is issuing the majority of its publications within the time period allowed. The target of 85% would have been met, but one month's figures distort the overall achievement as the HFEA was awaiting the publication of the new Patients' Guide.

3. Data entry unit costs per DI/IVF treatment

Month	Average Unit Cost per data entry for DI/IVF over 12months
April 2000 – March 2001	£0.79

Summary: The target unit cost figure was reduced twice during the course of the financial year from £0.92 to £0.70. At the beginning of the year, the figures were well under target, but were not a true reflection of the picture. Towards the end of the period the target was exceeded because centres need to be contacted due to inaccuracies on the forms. The target unit cost is being maintained this year and it is hoped that the clinics will respond by being more accurate in their form completion.

4. HFEA performance against Government financial targets including:

Percentage of creditors paid with 30 days;

Month	Average % of creditors paid within 30 days
April 2000 – March 2001	96%

Percentage of Debts recovered within 60 days

Month	Average % of debts recovered within 60 days
April 2000 – March 2001	77%

Summary: The above figures compare favourably with other public sector organisations. The collection of debts were below the overall target of 85% was missed, but the overall level of debt was minimal and due to one bad set of figures over the Christmas period.

Human Fertilisation
and Embryology Authority

Accounts 2000-2001

FOREWORD

BACKGROUND

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7 November 1990 and began operating on 1st August 1991. The HFEA was created by the Human Fertilisation and Embryology Act 1990 to license and regulate human embryo research and specified forms of infertility treatment.

The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health.

Statutory Remit

One of the main statutory functions of the HFEA is to regulate, by means of a licensing system, centres undertaking infertility treatments involving the creation or use of human embryos outside the body, the storage or donation of embryos or gametes or research involving human embryos.

The HFEA is also required to maintain a register of information about all licensed treatments performed in the United Kingdom. This contains information about those receiving treatment, donors of gametes and embryos and any children born as a result of such treatments. At the age of 18 (or 16 if wishing to marry), people may enquire as to whether information held on the register shows that they were born as a result of this treatment, and, if so, whether they are related to a prospective spouse.

In addition, the HFEA has other statutory responsibilities including:

- publicising the services provided by it and by the centres it licenses;
- publishing a Code of Practice giving guidance to centres on how they should carry out licensed activities;
- giving information and advice to donors, to people seeking treatment or storage or to people considering such action; and
- keeping the field under review and providing advice to the Secretary of State for Health, if so requested.

PRINCIPAL ACTIVITIES

Licensing:

Below is a summary of the licensing activities undertaken from 1 April 2000 to 31 March 2001:

INSPECTIONS	2001	2000	1999
No. of licensed centres at 31 March	117	116	119
No. of inspection visits during year	114	109	106
No. of audit visits during year	21	25	28
No. of ICSI Practitioners inspected	20	22	35
No. of PGD Practioners inspected	2	1	0

ISSUE OF LICENCES	2001	2000	1999
No. of Licence Committee meetings	33	39	32
No. of items considered	293	328	315
No. of licences issued (Treatment & Storage)	56	110	92
No. of licences issued (Storage)	4	8	6
No. of licences issued (Research)	8	10	16

Established centres are subject to a three year licensing cycle composed of one full and two interim inspections.

The HFEA's Systems and Data Audit five year programme, commenced in October 1996, completed its fourth year. At 31st March 2001 a total of 108 audits had been carried out. The programme was established to ensure that centres and the HFEA are complying with their statutory obligations.

Information:

The HFEA collects data from all licensed centres about IVF and donor insemination treatments, their outcomes and about every donor. The HFEA published a Patients' Guide for 2000 giving the outcome data for individual clinics. This information is also published on the HFEA's website (www.hfea.gov.uk).

Policy:

The Authority agreed a draft of the 5th edition of the Code of Practice in March that was published in 2001/2. Guidance on egg sharing was issued in September 2000.

FINANCIAL REPORT

Performance against key financial targets

The HFEA is required to meet two key financial targets.

- i. to keep within the cash limit set by the Department of Health
- ii. to recover 70% of its cash limit from charges made to centres for licence fees.

i. Cash Limit

The cash limit set in 2000/2001 was £1,579,000. This amount was comprised of the agreed cash limit of £1,611,000 less an adjustment for excess resources of £32,000 received in 1999/2000.

In cash terms the HFEA received resources of £1,524,767 in 2000/2001 and therefore remained within its cash limit.

ii. Charges made to centres

The HFEA's second financial objective in 2000/01 was to recover 70% of its cash limit (i.e. £1,105,300) through the charges made to centres. The amount recovered in cash from charges to centres in 2000/1 was £1,218,436, which was 77% of the adjusted cash limit of £1,579,000 or an over-recovery of income of £113,136. This arose due to the timing of cash flows. Under Treasury rules the excess of £113,136 must be returned by the Department of Health to the Treasury, thereby reducing the cost of the HFEA to the public purse.

Costs recovered through charges on an accruals basis amounted to £1,241,022.

Income and Expenditure Account

The HFEA's financial targets are set in cash terms. The account for the year, however, is drawn up on an accruals basis. The income and expenditure operating deficit for 2000/2001 amounted to £144,239.

Payment of Creditors

The HFEA has adopted the principles of the "Better Payment Procedure Code", and works to ensure that all undisputed invoices are paid within 30 days. In 2000/2001 the HFEA paid 96% of invoices within 30 days (1999/2000 88%) and 99% were paid within 60 days (1999/2000 99%).

Charitable Donations

There have been no charitable donations.

Equal Opportunities

The HFEA is an equal opportunities employer with a policy of providing equality of opportunity for all staff members and job applicants. The HFEA does not discriminate against anyone on the grounds of age, race, colour, ethnic or national origin, gender, marital status, responsibility for children or dependants, disability, sexual orientation or religious or political beliefs.

Consultation with Employees

The HFEA's policy is to involve staff and to consult them on relevant matters such as health, safety and welfare. To encourage an effective work/life balance, staff are able to work flexi-time with the agreement of their line manager. Issues that may be of interest or concern are discussed at regular staff meetings. A new appraisal system was introduced during the year to improve performance review and the development of staff.

Environment

The HFEA strives to work in an environmentally friendly manner. It makes a positive effort to recycle paper and to manage its premises and resources in an efficient way.

HFEA Membership

The HFEA's full complement is a Chairman, Deputy Chairman and nineteen members. Members who have served the HFEA for some period of the year 2000/2001 are listed in Annex A.

FUTURE DEVELOPMENTS

In addition to the work involved in licensing, policy, information and communications, the following are some of the high priority issues being taken forward by the HFEA in the financial year 2001/2002:

- to continue to assess licensing procedures and processes and their costs
- to implement and monitor the second cycle of the systems and data audit programme
- to publish the fifth edition of the Code of Practice
- to implement the ending of the first period of statutory storage
- in partnership with the Human Genetics Commission, to complete work on the formulation of the HFEA's policy on the licensing of pre-implantation genetic diagnosis
- to set up a programme for the phased introduction of electronic data interchange by centres
- to develop systems for the auditing of core data on the register
- to take forward, as appropriate, the recommendations of the second Quinquennial Review.

- to review the accommodation requirements of the HFEA. The lease of Paxton House has a break point at 31 March 2002. It is likely that the break clause will be invoked, as the HFEA requires additional office space.

Signed: Dr Maureen Dalziel

Position: Chief Executive

Date: 12th July 2001

Annex A Membership of the Human Fertilisation and Embryology Authority for the year ended 31 March 2001

Mrs Ruth Deech (Chairman)
Lady Julia Tugendhat (Deputy Chairman)
Mrs Jane Denton (Director of Sub-committees)
Professor Brenda Almond
Dr Sue Avery
Professor David Barlow
Professor Thomas Baldwin (appointed 2/3/01)
Professor Peter Braude
Professor Iain Cameron (appointed 5/3/01)
Mrs Moira Coath (retired 6/11/00)
Professor Christine Gosden
Professor Andrew Grubb
Professor Henry Leese

Professor Stuart Lewis
Dr Anne McLaren
Dr Sadia Muhammed
Ms Sara Nathan
Ms Sharmila Nebhrajani
Rt Rev'd Dr Michael Nazir-Ali
Dr Francoise Shenfield
Mrs Jean Smith
Professor Allan Templeton (retired 6/11/00)
Mrs Lis Woods

Statement of Authority's and Chief Executive's Responsibilities

Under section 6(1) of the Human Fertilisation and Embryology Act 1990 the Human Fertilisation and Embryology Authority is required to prepare a statement of accounts for each financial year in the form and on the basis determined by the Secretary of State, with the consent of the Treasury. The accounts are prepared on an accruals basis, and must show a true and fair view of the Authority's state of affairs at the year-end and of its income and expenditure, total recognised gains and losses and cash flow for the financial year.

In preparing the accounts the Authority is required to:

- observe the accounts direction issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed, and disclose and explain any material departures in the financial statements;
- prepare the financial statements on the going concern basis, unless it is inappropriate to presume that the Authority will continue in operation.

The Accounting Officer of the Department of Health has designated the Chief Executive of the Human Fertilisation and Embryology Authority as the Accounting Officer for the Authority. Her relevant responsibilities as Accounting Officer, including her responsibility for the propriety and regularity of the public finances for which she is answerable and for the keeping of proper records, are set out in the Non-Departmental Public Bodies' Accounting Officer Memorandum.

Statement on the System of Internal Financial Control

As Accounting Officer I acknowledge my responsibility for ensuring that an effective system of internal financial control is maintained and operated by the HFEA.

The system can provide only reasonable, and not absolute, assurance that assets are safeguarded, transactions authorised and properly recorded and that material errors or irregularities are either prevented or would be detected within a timely period.

The system of internal financial control is based on a framework of regular management information, administrative procedures, including the segregation of duties, and a system of delegation and accountability. In particular, it includes:

- comprehensive budgeting systems with an annual budget report which is reviewed by the Organisation and Finance Committee (OFC) and agreed by the Authority. In addition, the OFC receives a biannual budget report;
- regular reviews by senior managers of monthly and biannual financial reports which indicate financial performance against forecasts;
- setting targets to measure financial and other performance; and
- clearly defined capital investment procedures.

The accountancy firm, KPMG, is the HFEA's internal auditor, and operates to standards defined in the Government Internal Audit Manual. The work of the internal auditor is informed by an analysis of the risk to which the body is exposed, and annual internal audit plans are based on this analysis. The analysis of risk and the internal audit plans are approved by both the HFEA's Audit Committee and by me. A report on internal audit activity in the HFEA is provided to the Audit Committee. The report includes an assessment of the adequacy and effectiveness of the body's system of internal financial control.

My review of the effectiveness of the system of internal financial control is informed by the work of the internal auditors, the Audit Committee, which oversees the work of the internal auditors, those HFEA executive managers

who have responsibility for the development and maintenance of the financial control framework and comments made by the external auditors in their management letter and other reports.

Where recommendations are made by the internal or external auditors, action plans are agreed by senior managers and myself for implementation of those recommendations. The plans set out the action to be taken and the timetable for implementation. Progress against an action plan is monitored by senior managers and by the HFEA's Audit Committee, which considers all audit reports and the actions undertaken by management to correct weaknesses highlighted. Internal and external auditors also follow up recommendations made in previous reports.

Formal procedures for Finance and Audit have been drawn up and are incorporated in the staff manual. The HFEA regularly reviews and updates these procedures to improve and strengthen its system of internal controls. The finance procedures were updated in 2000/2001.

As Accounting Officer I am aware of the recommendations of the Turnbull Committee and I am taking reasonable steps to comply with the Treasury's requirement for a statement of internal control to be prepared for the year ended 31 March 2002 in accordance with guidance to be issued by them.

Signed: Maureen Dalziel
Position: Chief Executive
Date: 12th July 2001

THE CERTIFICATE OF THE COMPTROLLER AND AUDITOR GENERAL TO THE HOUSES OF PARLIAMENT

I certify that I have audited the financial statements on pages 53 to 70 under Section 6(4) of the Human Fertilisation and Embryology Act 1990. These financial statements have been prepared under the historical cost convention as modified by the revaluation of certain fixed assets and the accounting policies set out on pages 57 and 58.

Respective responsibilities of the Authority, the Chief Executive and Auditor

As described on page 47 the Authority and Chief Executive are responsible for the preparation of the financial statements and for ensuring the regularity of financial transactions. The Authority and Chief Executive are also responsible for the preparation of the Foreword. My responsibilities, as independent auditor, are established by statute and guided by the Auditing Practices Board and the auditing profession's ethical guidance.

I report my opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and the Secretary of State for Health directions made thereunder, and whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. I also report if, in my opinion, the Foreword is not consistent with the financial statements, if the Authority has not kept proper accounting records, or if I have not received all the information and explanations I require for my audit.

I review whether the statement on pages 48 and 49 reflects the Authority's compliance with Treasury's guidance 'Corporate governance: statement on the system of internal financial control'. I report if it does not meet the requirements specified by Treasury, or if the Statement is misleading or inconsistent with other information I am aware of from my audit of the financial statements.

Basis of opinion

I conducted my audit in accordance with Auditing Standards issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Authority and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Human Fertilisation and Embryology Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by error, or by fraud or other irregularity and that, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. However, the evidence available to me was limited in respect of the £1.2 million recorded as licence fee income in the accounts. This amount is based on the number of patient treatments reported by clinics to the Authority. As I am not permitted access to patients'

records, I rely on the work of the Authority's own staff in validating the number of treatments reported. The results of their sample testing indicated inaccuracies in reporting by clinics and there were no other satisfactory audit procedures that I could adopt to confirm that licence fees were properly calculated.

In forming my opinion I have also evaluated the overall adequacy of the presentation of information in the financial statements.

Qualified opinion arising from limitation in audit scope

In my opinion:

- except for any adjustments that might have been found necessary had I been able to obtain sufficient evidence concerning licence fee income, the financial statements give a true and fair view of the state of affairs of the Human Fertilisation and Embryology Authority at 31 March 2001 and of the deficit, total recognised gains and losses and cash flows for the year then ended and have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State; and
- in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Details of these matters are set out in my report.

John Bourn
Comptroller and Auditor General
Date: 13 July 2000

National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON SW1W 9SP

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL

Accounts of the Human Fertilisation and Embryology Authority 2000-01

Background

1. The Human Fertilisation and Embryology Authority was set up in 1991 under the Human Fertilisation and Embryology Act 1990. The Authority's principal tasks are to license and monitor clinics carrying out *in vitro* fertilisation, donor insemination and human embryo research.
2. Under Section 16 of the Act, the Authority is required to charge fees for the issue and renewal of licences. These licence fees consist of an initial fee plus an additional fee based on the number of treatment cycles performed by the clinic. With the approval of the Secretary of State and the Treasury, current fees rates were set in 2000 with the target of recovering 70 per cent of the Authority's total costs. In 2000-01, the Authority's accounts report total income from licence fees of £1.2 million, which was 72% of the Authority's running costs.

Basis for the qualified audit certificate

3. Licensed centres must notify the Authority of the outcome of each treatment cycle so that fees can be charged on this basis. The Authority employs a systems data auditor to conduct a rolling programme of visits to licensed centres to ensure that data returns are accurate and complete. Twenty licensed centres were visited during 2000-01. The results of the data audits showed that the returns from some centres did not include all of the treatment cycles where the outcome was known and that, as a result of under-reporting, the Authority may not be recovering all of the licence fee income due.
4. In normal circumstances, I would undertake additional procedures to verify the income due but in this case I was unable to do so. This is because, under Section 33 of the Act it is an offence to disclose to any party information held on the Register. The Act only permits access to the Authority's own staff and I therefore have no access to the information used to calculate licence fees, nor to the records maintained by individual centres.

Limitation of scope

5. Because of the legal restrictions on my access to information there are no other satisfactory audit procedures that I can adopt to confirm the accuracy of the licence fee income which should have been collected. Therefore I have qualified my audit opinion because the possible effect of the limitation of the scope of my audit is material.

Action taken by the Authority

6. The Authority recognises that the current system for calculating licence fees is unsatisfactory and they are already actively engaged in examining alternative bases for determining licence fees.
7. The Authority has assured me that it has action plans in place and will continue to liaise with my staff.

John Bourn
Comptroller and Auditor General
Date: 13th July 2001

National Audit Office
157-197 Buckingham Palace Road
Victoria
LONDON SW1W 9SP

Income and Expenditure Account for the year ended 31 March 2001

	Notes	£	1999/2000 £
Income			
Gross income	2	1,555,252	1,530,960
Transfer from Deferred Government Grant	12	73,419	58,961
		1,628,671	1,589,921
Expenditure			
– Staff Costs	3	969,503	932,093
– Other Operating Charges	4	736,311	733,610
– Depreciation	5	67,096	40,954
		1,772,910	1,706,657
Total Expenditure			
Operating (Deficit)	6	(144,239)	(116,736)
– Notional Interest(Capital Charges)	1	(15,132)	(23,200)
		(159,371)	(139,936)
(Deficit) on Ordinary Activities			
– Write back of Notional Interest		15,132	23,200
– Write back of Notional Superannuation		–	79,336
		(144,239)	(37,400)
Deficit for the financial year			
Retained surplus brought forward		212,048	249,448
		67,809	212,048
Retained surplus carried forward			

All operations are continuing

The notes on pages 57–70 form part of these accounts.

Statement of Total Recognised Gains and Losses for the year ended 31 March 2001

	Notes	£	1999/2000 £
Deficit for the financial year		(144,239)	(37,400)
Unrealised surplus on revaluation of fixed assets	5	855	(1,085)
Total recognised losses for the year		<u>(143,384)</u>	<u>(38,485)</u>

The notes on pages 57–70 form part of these accounts

Balance Sheet as at 31 March 2001

	Notes	£	31 March 2000 £
Fixed Assets	5	85,860	138,677
Current Assets			
– Debtors: Amounts falling due within one year	7	241,461	195,731
– Cash at bank and in hand		16,095	79,054
Creditors: Amounts falling due within one year	8	(189,748)	(62,738)
Net Current Assets		67,808	212,047
Total Assets less Current Liabilities		153,668	350,724
Financed By			
Accruals and Deferred Income			
– Deferred government grant	12	74,893	128,565
Capital and Reserves			
– Income and Expenditure account	12	66,408	212,048
– Revaluation Reserve	12	12,367	10,111
		153,668	350,724

The notes on pages 57–70 form part of these accounts

Dr Maureen Dalziel
Chief Executive

Date: 12 July 2001

Cash Flow Statement for the year ended 31 March 2001

	Notes	£	1999/2000 £
Operating Activities			
Net Cash Outflow/Inflow	19	(62,959)	20,260
Capital Expenditure			
– Purchase of Fixed Assets	5	(19,747)	(25,838)
Net Cash (Outflow) before financing		<u>(82,706)</u>	<u>(5,578)</u>
Financing			
– Receipts of Government Grants for fixed assets	12	19,747	25,600
– Transfer from revenue grant	12	–	238
Net cash inflow from financing		<u>19,747</u>	<u>25,838</u>
(Decrease)/Increase in Cash	19	<u>(62,959)</u>	<u>20,260</u>

The notes on pages 57–70 form part of this account

NOTES TO THE ACCOUNT

1. Accounting policies

(a) Accounting convention

The HFEA's accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Determination issued by the Secretary of State for Health in May 1997 (reproduced as an appendix to these accounts).

These accounts are prepared, in accordance with applicable accounting standards, under the historical cost convention modified to allow for the revaluation of fixed assets. Without limiting the information given, the accounts meet the accounting and disclosure requirements of the Companies Acts and accounting standards issued or adopted by the Accounting Standards Board so far as those requirements are appropriate.

(b) Fixed assets

Fixed Assets include tangible fixed assets and the costs of acquiring or creating computer systems or software. Only items, or groups of related items, costing £1,000 or more, are capitalised. Those costing less are treated as revenue expenditure. Assets are indexed annually using the Central Statistical Office Index for computers and other information processing equipment, and appropriate Health Service Cost indices for other assets. Gains and losses arising on indexation are normally taken to the revaluation reserve. However, deferred government grant is released to match downward indexation of particular assets when there are no related existing credits within the revaluation reserve.

(c) Depreciation

Depreciation is provided on all tangible fixed assets at rates calculated to write off the cost of each asset evenly over its expected useful life. Expected useful lives are as follows:

Computer equipment and software	3 years
Office equipment	4 years
Furniture, fixtures and fittings	4 years

Installations and improvements to leasehold property are depreciated over the lower of 10 years or the remainder of the lease term.

(d) Operating leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

(e) Register of information

Expenditure on development of the computer programme for the Register of Information is charged to the Income and Expenditure Account as it is incurred.

(f) Government grants

Government grants received for revenue expenditure are credited to income in the year to which they relate.

Government grants received for capital expenditure are credited to a Deferred Government Grant Reserve and released to the Income and Expenditure Account to match depreciation and downward indexation, where appropriate.

(g) Notional charges

In accordance with Treasury guidance, notional interest at 6% of the average capital employed has been charged in the Income and Expenditure Account amounting to £15,132 (1999/00 – £23,200).

2. Gross Income

The gross income is made up of Government grants, made on a cash basis, which are offset by licence fee and other income which are recorded on an accruals basis. Government grants received for capital expenditure are credited to a Deferred Government Grant Reserve (note 1). Where licence fee income collected exceeds 70% of cash limit, the balance is surrendered to the Department of Health.

	2000/2001 £	1999/2000 £
Department of Health Class II, Vote 2	1,280,000	1,299,000
Scottish Executive	153,000	146,000
National Assembly of Wales	77,000	74,000
Northern Ireland Assembly	43,000	41,000
	1,553,000	1,560,000
Less transfer to Deferred Government Grant	0	(238)
	1,553,000	1,559,762
Cash/Accruals Adjustment	2,252	(28,802)
	1,555,252	1,530,960
Gross Income reported in Income and Expenditure Account		

Analysis of Income

Recovered in Licence Fee Income	1,241,022	1,583,760
Other Income	1,410	728
Superannuation Receipts	0	40,877
Capital grant	(19,747)	(25,838)
Cash to be surrendered to Department of Health	0	(68,567)
Accrued grant income	32,567	
Cash received from Department of Health	300,000	
	1,555,252	1,530,960

3. Staff Costs

	2000/2001 £	1999/2000 £
All Staff		
Salaries – HFEA Staff	670,481	637,581
Salaries – Seconded Staff	31,477	61,687
Social Security Costs	50,748	53,044
Superannuation Costs – Seconded Staff	5,820	10,894
Net Superannuation Costs – Executive Staff	93,142	0
Notional Superannuation Charge 1999/2000	–	79,336
Agency/Temporary Staff	19,510	19,048
	871,178	861,590
Members' Costs	98,325	70,503
	969,503	932,093

The average monthly number of staff employed, including secondees, during the year was as follows:

	2000/2001 No.	1999/2000 No.
Management	4	5
Administrative	30	28
	34	33

Remuneration of key management

Chief Executive

Emoluments (excluding pension fund contributions):

Salary (to 15 October 2000)	31,459	53,495
Bonus payments	0	250
Total	31,459	53,745

Pension entitlements

The former Chief Executive was seconded to the HFEA from the Home Office and is an ordinary member of the Principal Civil Service Pension Scheme (see also note 9). Employer Contributions from 1 April to 15 October 2000 amounted to £5,820 (1999/00 – £9,556). The total accrued pension disclosed below excludes pension benefits arising from the purchase of added years or additional voluntary contributions. It also excludes the value of pension benefits transferred from other schemes.

	£
Real increase in pension at 60 during 2000/2001	564
Total accrued pension at 60 as at 15/10/00	7,430

Acting Chief Executive

	£
Emoluments Salary	44,122

The Acting Chief Executive is a member of the HFEA Pension Scheme (see also note 10). Employer contributions for the year amounted to £7,280. The total accrued pension disclosed below exclude pension benefits arising from the purchase of added years, additional voluntary contributions or the value of the pension benefits transferred from other schemes.

	£
Real increase in pension at 60 during 2000/01	1,003
Total accrued pension at 60 as at 31/03/01	5,100

Other Senior Managers

The Resource Accounting Manual requires the HFEA to provide information on the age, salary and pension rights of the named individuals who are the “most senior managers” of the HFEA, subject to the individuals concerned consenting to disclosure. However, the following senior managers – Derek Hodge and Allan Wright – have declined to give their consent to the publication of their personal details and such information is not therefore included in this note.

Remuneration of Authority Members

Chairman

	2000/2001 £	1999/2000 £
Remuneration	15,420	8,440

No pension contributions were made on behalf of the Chairman in 2000/2001 (1999/2000 – nil).

	£	£
Members		
Total fees paid to members including Chairman	93,120	68,401
Social Security Costs	5,205	2,102
	98,325	70,503

The Deputy Chairman received a fee of £175 per day (1999/2000 £147). Other Board Members received a fee of £160 per day (1999/2000 £135). No pension contributions were paid on behalf of any Board Member. Remuneration payable to individual members for attendance at meetings and inspections during the financial year is as follows:

	£
Lady Julia Tugendhat (Deputy Chairman)	5,695
Professor Brenda Almond	3,680
Dr Sue Avery	5,600
Professor David Barlow	3,040
Professor Thomas Baldwin (appointed 2/3/01)	160

Professor Peter Braude	3,840
Professor Iain Cameron (appointed 5/3/01)	0
Mrs Moira Coath (retired 6/11/00)	1,120
Mrs Jane Denton	8,840
Professor Christine Gosden	3,680
Professor Andrew Grubb	3,200
Professor Henry Leese	5,760
Professor Stuart Lewis	6,720
Dr Anne McLaren	2,720
Dr Sadia Muhammed	4,640
Ms Sara Nathan	4,640
Ms Sharmila Nebhrajani	2,880
Rt Rev'd Dr Michael Nazir-Ali	960
Dr Francoise Shenfield	3,200
Mrs Jean Smith	2,080
Professor Allan Templeton (retired 6/11/00)	1,120
Mrs Lis Woods	4,640

4. Other Operating Charges

	2000/2001 £	1999/2000 £
Operating lease payments		
– land and buildings	110,450	110,450
– other leases	12,203	17,406
Accommodation	100,399	90,730
Travel & subsistence	112,169	101,448
Attendance fees – Inspectors	26,267	23,401
Professional & administrative fees	79,699	134,136
Audit fees	12,000	11,500
Register of information	15,019	10,691
Stationery, photocopying & printing	65,764	96,493
Telephones & postage	44,645	42,979
Training & development	29,235	17,585
Recruitment & advertising	68,950	17,065
Conferences & meeting expenses	12,449	12,418
Library & reading materials	8,524	9,436
Sundry office equipment	18,458	19,456
Miscellaneous	13,757	13,931
Permanent diminution in value of fixed assets	6,323	4,485
Provision for Doubtful Debts	–	–
Total	736,311	733,610

5. Fixed Assets as at 31 March 2001

	Computer Equipment £	Office Equipment £	Furniture & Fittings £	Installations £	Totals £
Cost/valuation as at 31 March 2000	80,152	57,687	98,116	118,784	354,739
Additions	19,747	—	—	—	19,747
Disposals	(22,421)	(845)	—	—	(23,266)
Revaluation	(10,390)	1,563	(98)	(119)	(9,044)
As at 31 March 2001	67,088	58,405	98,018	118,665	342,176
Depreciation as at 31 March 2000	47,596	26,595	94,020	47,851	216,062
Charge for the year	19,245	10,457	1,963	35,431	67,096
Disposals	(22,421)	(845)	—	—	(23,266)
Revaluation	(4,142)	708	(94)	(48)	(3,576)
As at 31 March 2001	40,278	36,915	95,889	83,234	256,316
Net Book Value (NBV)					
At 31 March 2001	26,810	21,490	2,129	35,431	85,860
At 31 March 2000	32,556	31,092	4,096	70,933	138,677
Increase (Decrease) in NBV	(5,746)	(9,602)	(1,967)	(35,502)	(52,817)

6. Operating (Deficit)/Surplus

The activities of the Authority have contributed to the Operating Deficit as follows:

	LICENSING		OTHERS		TOTAL	
	2000/2001	1999/2000	2000/2001	1999/2000	2000/2001	1999/2000
	£	£	£	£	£	£
INCOME						
Licence Fees	1,241,022	1,583,760	–	–	1,241,022	1,583,760
Other	–	–	1,410	41,605	1,410	41,605
Net cash surrendered to/ received from the Department of Health	–	–	332,567	(68,567)	332,567	(68,567)
Transfer to Deferred Government Grant	–	–	(19,747)	(25,838)	(19,747)	(25,838)
Transfer from Deferred Government Grant			73,419	58,961	73,419	58,961
Total	1,241,022	1,583,760	387,649	6,161	1,628,671	1,589,921
EXPENDITURE						
Staff Costs	(621,978)	(585,940)	(347,525)	(346,153)	(969,503)	(932,093)
Depreciation	(33,548)	(20,477)	(33,548)	(20,477)	(67,096)	(40,954)
Other Charges	(501,438)	(509,560)	(234,873)	(224,050)	(736,311)	(733,610)
Total	(1,156,964)	(1,115,977)	(615,946)	(590,680)	(1,772,910)	(1,706,657)
Operating (Deficit)/Surplus	84,058	467,783	(228,297)	(584,519)	(144,239)	(116,736)

The above information is given to satisfy the disclosures required by HM Treasury Fees and Charges Guide not those required by Statement of Standard Accounting Practice No 25 (SSAP 25), "Segmental Reporting"

Statutory activities classified as "other" include maintaining the Register of Information, publicising the Authority's services, giving advice and reviewing the field of human fertilisation and embryology.

7. Debtors

		31 March 2000
	£	£
Licence fee & Accrued Income	119,903	97,502
Other debtors	12,971	14,394
Pre-payments	108,587	83,835
	241,461	195,731

8. Creditors: Amounts falling due within one year

		31 March 2000
	£	£
Trade creditors	79,991	1,743
Other taxes and social security	6,536	2,680
Department of Health	0	32,567
Accruals	103,221	25,748
	189,748	62,738

9. Pension Arrangements (Seconded Staff)

Seconded staff belong to the Principal Civil Service Pension Scheme. For 2000/2001, contributions of £5,820 (1999/2000 – £10,894) were made to the Paymaster General for seconded staff at rates determined from time to time by the Government Actuary and advised by the Treasury. The rate for 2000/2001 for non-industrial staff in salary band 4 (£54,001 and over) is 18.5%.

10. Pension Arrangements (HFEA Staff)

To 31/3/2000 the HFEA operated its own pay-as-you-go scheme to provide retirement and related benefits based on individual final emoluments to all eligible employees. The scheme is non-contributory and is analogous to the Principal Civil Service Pension Scheme. The scheme is funded on a pay-as-you-go basis from Grant in Aid. Pension liabilities are charged to the Income and Expenditure Account in the year of account. Members contributed 1.5% of annual salary to cover spouses' pensions. These contributions (1999/2000 £9,160) and any transfer values received from other organisations were classified as current income and any benefits paid were treated as current expenditure (1999/2000 – £778).

The HFEA has been negotiating for some months for bulk admission of its active scheme members to the Principal Civil Service Pension Scheme (PCSPS) as of 1 April 2000. The Order enabling the transfer was laid before Parliament on 26 April 2001. Following the final transfer to the PCSPS, HFEA superannuation will be administered by Paymaster and widowers' contributions deducted from staff salaries will be paid to them. The HFEA is liable for the annual payment of accruing superannuation liability contributions (ASLCs) calculated as a percentage of salary. The liability for 2000/1 amounts to £91,841.

The Government Actuary estimates that the cost of the transfer of accrued pension liabilities amounts to £531,800. The final figure will depend on the outcome of discussions relating to the treatment of those members of staff who left after 1 April 2000 but before the Order was laid on 26 April 2001 but any adjustment is not expected to be material. The Treasury has confirmed to the Department of Health that it is prepared to cover this cost.

Employees who left prior to 1 April 2000 cannot be admitted to the PCSPS. Their accrued pension rights will be preserved in the closed HFEA Pension Scheme and the HFEA will be liable for payment of benefits. The Government Actuary carried out an actuarial valuation of the liabilities of the HFEA scheme as at 31/3/01. The capitalised value as at 31 March 2001 of expected future benefit payments under the Human Fertilisation & Embryology Authority Pension Scheme, for benefits accrued in respect of former employment prior to 31 March 2001 has been assessed using the methodology and assumptions set out below. The results are as follows:

Value of Liabilities	£ 000
Pensions in Payment	0
Deferred Pensions	109
Total	109

Methodology

The value of the liabilities has been obtained using the projected accrued benefits method.

Assumptions

The principal financial assumptions adopted for the pension assessment made in relation to this statement are an investment return in excess of price increases of 3.5% p.a. (pension benefits under the scheme are increased in line with prices), and an investment return in excess of earnings increase of 2% p.a. The demographic assumptions adopted for the assessments are derived from the experience of the corresponding sections of the membership of the PCSPS.

11. Post balance sheet events

Except for the admission Order to the PCSPS (see note 10) there have been no post balance sheet events.

12. Deferred Government Grant, Capital and Reserves

	Deferred Government Grant £	Income and Expenditure £	Revaluation Reserve £
Balance at 31 March 2000	128,565	212,048	10,111
Movements in Year:			
Revaluation of fixed assets			855
Transfer to Revaluation Reserve		(1,401)	1,401
2000/2001 capital grant	19,747		
Transfer from revenue grant	—		
Transfer to income & expenditure	(73,419)		
(Deficit) for the year		(144,239)	
Balance at 31 March 2001	<u>74,893</u>	<u>66,408</u>	<u>12,367</u>

13. Financial commitments

The HFEA is committed to make the following operating lease payments during the next financial year.

	2000/2001 £	1999/2000 £
Land and Buildings		
Leases which expire in over 5 years	110,450	110,450
Other Leases		
Leases which expire within 1 year	0	0
Leases which expire within 2 to 5 years	12,204	12,204

14. Capital Commitments

At the balance sheet date the HFEA had no capital commitments.

15. Contingent Liabilities

The HFEA had no contingent liabilities at the balance sheet date.

16. Material Losses

The HFEA had no material losses in the year 2000/2001.

17. Related Party Transactions

The Department of Health is regarded as a related party. During the year the HFEA has had various material transactions with the Department and with some NHS Trusts for which the Department of Health is regarded as the parent Department.

None of the HFEA Members, key managerial staff or other related parties have undertaken any material transactions with the HFEA during the year.

18. Performance against key financial targets

The HFEA has two key financial targets.

- The HFEA must ensure that it remains within the cash limit set by the Department of Health. In the year 2000/2001, resources received and retained in cash terms amounted to £1,524,767. Actual cash expenditure was £1,587,891. (See the Foreword, page 43).
- The HFEA was also required to recover 70% of its cash limit from licence fees. The amount raised in cash from licence fees in 2000/2001 was £1,218,436, which was 77 % of the adjusted cash limit.

19. Notes to the Cash Flow Statement

1. Reconciliation of operating deficit to net cash inflow from operating activities:

	£	1999/2000 £
Operating (deficit)	(144,239)	(116,736)
Notional superannuation charge	—	79,336
Depreciation charges	67,096	40,954
Downward indexation charge	6,323	4,485
(Increase)/Decrease in debtors	(45,730)	30,219
Increase in creditors	127,010	40,963
Transfer from deferred government grant	(73,419)	(58,961)
Net Cash Inflow from Operating Activities	(62,959)	20,260

2. Analysis of Changes in cash

	At 31 March 2000	Cash Flows	At 31 March 2001
Cash at Bank and in Hand	79,054	(62,959)	16,095

Appendix

The Human Fertilisation and Embryology Authority

Accounts Determination

The Secretary of State, with the approval of the Treasury, in pursuance of section 6 of the Human Fertilisation and Embryology Act 1990, hereby gives the following determination:

1. Direction given by the Secretary of State

In this determination "the Authority" means the Human Fertilisation and Embryology Authority.

2. Form of Accounts

The Authority shall prepare accounts for the financial year ended 31 March 1997 and subsequent financial years comprising:

- a) a foreword;
- b) an income and expenditure account;
- c) a balance sheet;
- d) a cash flow statement; and
- e) a statement of total recognised gains and losses;

including such notes as may be necessary for the purposes referred to in the following paragraphs.

3.

The accounts shall give a true and fair view of the income and expenditure and cash flows for the financial year, and the state of affairs as at the end of the financial year.

4.

Subject to this requirement, the accounts shall be prepared in accordance with:

- a) generally accepted accounting practice in the United Kingdom (UK GAAP);
- b) The disclosure and accounting requirements contained in "The Fees and Charges Guide" (in particular those relating to the need for appropriate segmental information for services or forms of service provided) and in other guidance which the Treasury or the Secretary of State may issue from time to time in respect of accounts which are required to give a true and fair view;
- c) The accounting and disclosure requirements given in "Government Accounting" and in "Executive NDPBs: Annual Reports and Accounts guidance; as amended or augmented from time to time:

insofar as these are appropriate to the Authority and are in force for the financial year for which the statement of accounts is to be prepared.

5.

Clarification of the application of the accounting and disclosure requirements of the Companies Act and accounting standards is given in Schedule 1 attached. Additional disclosure requirements are set out in Schedule 2 attached.

6.

The income and expenditure account and balance sheet shall be prepared under the historical cost convention modified by the inclusion of:

- a) fixed assets at their value to the business by reference to current costs; and
- b) stocks valued at the lower of net current replacement cost (or historical cost if this is not materially different) and net realisable value.

7.

This accounts determination supersedes that dated 26 April 1996 and shall be reproduced as an appendix to the accounts.

Date: 6 May 1997

Signed by the authority of the Secretary of State for Health

P. KENDALL

**Branch Head (RMF-EAC Division)
Department of Health**

Schedule 1

Application of the accounting and disclosure requirements of the Companies Act and Accounting Standards

Companies Act

1.

The disclosure exemptions permitted by the Companies Act shall not apply to the Authority unless specifically authorised by the Secretary of State with the approval of the Treasury.

2.

The Companies Act requires certain information to be disclosed in the Directors' Report. To the extent that it is appropriate, the information relating to the Authority shall be contained in the foreword.

3.

When preparing its income and expenditure account, the Authority shall have regard to the profit and loss format 2 prescribed in Schedule 4 to the Companies Act 1985 (as amended).

4.

When preparing its balance sheet, the Authority shall have regard to the balance sheet format 1 prescribed in Schedule 4 to the Companies Act 1985 (as amended). The balance sheet totals shall be struck at 'Total assets less current liabilities'.

5.

The Authority is not required to provide the additional information required by paragraph 33 (3) of Schedule 4 to the Companies Act 1985.

6.

The foreword and balance sheet shall be signed by the Chief Executive to the Authority and dated.

Accounting Standards

7.

The Authority is not required to include a note showing historical cost profits and losses as described in FRS3.

8.

The Authority shall adopt the Financial Reporting Standard for Smaller Entities unless specifically approved by the Treasury.

Schedule 2

Additional disclosure requirements

1.

The foreword shall, inter alia:

- a) State that the accounts have been prepared in a form determined by the Secretary of State with the approval of the Treasury in accordance with Section 6 of the Human Fertilisation and Embryology Act 1990;
- b) Include a brief history of the Authority and its statutory background.

2.

The notes to the accounts shall, inter alia:

- a) Include details for the accounting policies adopted;
- b) Provide further explanations of figures in the accounts where it is considered appropriate for a proper understanding of the accounts;
- c) Include details of the key corporate financial targets set by Ministers together with the performance achieved.

